Legal Critique of Bioexploitation

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-All will start by loving a person- Ozan Siso

Declaration

This dissertation has not been submitted as an exercise for a degree at this or any other university.

This dissertation is, except where otherwise indicated, entirely my own work.

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Summary

The thesis levels its criticism at what lies within the political economy of the scientific and medical production. In pursuance of a socio-legal critique of clinical trials, the research discussed the exploitative nature of these medical experiments where participants were left defenceless by the legal framework to transnational companies' abusive practices fuelled by the desire of generating more profit. Conceptualising ethics pertaining the use of clinical trials in rhizomatic lines, the research goes on theorising the relationship of the politico-legal and the economic through a meshing of historical materialism with biopolitics. Such Marxian analysis of capital when combined with Foucaultian discussion of power cast light upon the class essence of laws governing the medical trials in a holistic manner. Exploring the structural exploitation in this manner, the research identifies the clinical trial participants as a labour force whose lives are reduced to a marketable value; it is, in fact, the final proposition of the research that the only avenue to debilitate the participants' exploitation can be achieved through their acknowledgement by the law as employees with contractual and statutory rights as such.

Clinical trials have predominantly been under the influence of mainstream bioethics. A fresh outlook based upon critical theory, which the thesis seeks to provide, is necessary to reconsider the guidelines and legislations, most of which have been ratified and implemented after infamous experiments such as those by the Nazi regime and the scandalous Tuskegee Syphilis experiment in the United States, in coherence with the concepts of exploitation and biocapitalism. The thesis asserts that clinical trial participants cannot be protected by the available legal framework and mainstream bioethics for the current policies in the subaltern nations do not afford the same protection to as it is afforded in their affluent counterpart which is in fact why the transnational companies conduct most of their research in the peripheral with the assurance of impunity. Such legal immunity rests mostly on the neoliberal policies adopted by the polities in these countries for which science is a capitalist venture instead of a field to assist the human civilization in the societal betterment. Rose describes this as a shift from the politics of health to a politics of life where clinical trials are the "experimental machinery of biocapital," thus rendering the peripheral an experimental site. To address this issue, law has to be domestically and internationally tailored accordingly to define clinical trial participants as workers, thus basing their protection on the foot of contractual obligations for the lack of such recognition results in the severe harm and exploitation of the clinical participants in the peripheral by the pharmaceutical and biotech industry.

The thesis is divided into eight parts. The second chapter will provide a brief critique of clinical trials. The following chapter explores the principles of bioethics, from mainstream to critical. Chapter 4 offers the law surrounding the protection on human subject research. Chapter 5 details the clinical trial practices in the U.S. by mainly dissecting it through case law on Alien Tort Statute. Chapter 6 examines two examples of global clinical trials as well as providing exploitation theories with a view to defending a Marxist concept of exploitation. Chapter 7 analysis the relatively new concept of biocapitalism and bieconomy in relation to clinical trial participants. Finally Chapter 9 argues that the best avenue for clinical trial participant protection and to demand accountability from the pharmaceutical industry, the clinical trial participants should be categorised as workers.

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1.Introduction

There has always been a tension between the advancement of science and the protection of human participants. Nevertheless, the world did not realise until the Nazi experimentations that there is a need for a comprehensive research ethics guideline. The abuse and the exploitation of the clinical trial participants benefitted for the advancement of life sciences have just changed form. Likewise, their exploitation has transformed, as the last decades has been a stage to the ever-going transmutation of the knowledge production which has been reflected in the economics of science. The advancement in life sciences has provided many opportunities and improved the quality of life, at least for the privileged classes of the affluent nations. However, problems ensued shortly. Traditionally science was under the dome of public sector and universities, more or less adhering to principles put forward by Robert Merton. Through the rapid growth in biotechnology sector the commercialisation of science started by way of intellectual property framework. Science became meta, it is no longer conducted to produce scientific knowledge and assist in human betterment rather it is not a capitalist venture. Rose describes this as a shift from the politics of health to a politics of life.[1] Consequently, as he observes, the pharmaceutical industry, is now situated "in what has been called the bioeconomy, an emerging practicotheoretical field where the life sciences and the capitalist regulatory system intersect."[2]

Law needs to perceive clinical trial participants' participation as work and until then pharmaceutical and biotech industry will continue to exploit, and especially severely harm the peripheral. The discussion of the concepts of exploitation and biocapitalism, will enable this thesis to argue that categorisation of clinical participants as workers is vital for their protection. Moreover, it will allow them to seek accountability from the private companies through the legislative protection and contractual obligations that will be afforded to them on the foot of their categorisation as workers. The clinical trial participants, this thesis will refer to, will be mainly enrolled in research that is characterised as research on vulnerable populations or research in developing countries, however this author will use the term peripheral. The U.S. based transnational companies that conduct or hire a contract research organisation (CRO) will be the main focus, as the U.S. companies have the highest rate of clinical trials conducted abroad. The total expenditure of U.S. pharmaceutical industry on research and development (R&D) was $ 51.2 billion.[3] Moreover, many scholars have impeached the corporate capital for the problems medicine face,[4] as well as for the U.S. led to the commercialisation of science.

Ethics pertaining the use of clinical trials have to be conceptualised in rhizomatic lines. Such an approach inhold Marx's economic analysis (substructure) and Foucault's biopolitics;

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[1] Rose, N., 'Politics of Life Itself: Biomedicine, Power, and Subjectivity in the Twenty-First Century', (Princeton: Princeton University Press 2007).
[2] Ibid 3.
[3] Statista, 'Research and development expenditure of the entire U.S. pharmaceutical industry from 1995 to 2014 (in billion U.S. dollars). Retrieved from: http://www.statista.com/statistics/265085/research-and-development-expenditure-us-pharmaceutical-industry/ <accessed on 14/06/2015>.
[4] See, for example, Jasso-Aguilar, R., Waitzkin, H., & Landwehr, A., 'Multinational corporations and health care in the United States and Latin America', (2004) Journal of Health and Social Behavior 136 and Navarro, V., 'Crisis, Health and Medicine: A Social Critique', (Methuen 1986).

substructure and superstructure respectively. This author pursuing a socio-legal critique of clinical trials, will ground itself upon two ecole, namely, Marx and Foucault. The former, will encompass exploitation, class and labour while the latter will help analyse power and recognition. The scholars sampled in this thesis is the congruence of the two schools. The two framework then supports each other.

1.1 Methodology

The research will avail of qualitative method in its attempt at the critical assessment of exploitation of clinical trial participants from a socio-legal approach. Most information is derived from library and internet, as typical with studies alike, in order to compile data from a variety of resources including, but not limited to, books, case reports, journal articles, historical records, and legislation. The materials are assessed accordingly to supply the existent academic cognizance with novel insight. The accepted wisdom will be questioned, examined and analysed through critical understanding.

1.2 Terminology

Affluent **-** The term is used by German-born American philosopher Herbert Marcuse who is widely known for his contribution to the Marxist and Freudian literature. In his most renowned work, *One-Dimensional Man: Studies in the Ideology of Advanced Industrial Society*,[5] Marcuse argued that the modern capitalist industrial society or, in his words, the "affluent" society confined its members in a "one-dimensional" existence of intellectual and spiritual poverty through the extensive us of consumer culture while repressing those who lacked the means to affluence.

Subaltern**-** Subaltern, herein used as conceptualised by Italian Marxian thinker Antonio Gramsci in *Notes on Italian History*,[6] refers to groups who lack political representation in the society as well as those existing. He argued that hegemony also functioned at a personal level, in the sense that some people did not regard themselves constituting as a part of an organised group.

Core-periphery**-** Core-periphery models, although vary in their descriptions and implications, are among widely used sociological world-systems analyses which are in general based on the Marxian theory of imperialism and explain various politico-economic (inter)dependencies between countries as well as within a country. This thesis utilizes the core-periphery model developed by Immanuel Wallerstein in his masterpiece the Modern World Systems.[7] Wallerstein conceptualized global power relations in terms of core, semi-periphery and periphery countries. To him, the capitalist world system was characterized by a set of mechanisms that continuously redistributed wealth from the periphery to the core; in his opinion, the world, however, was far from a simple bi-polarity and in between the developed core and the underdeveloped periphery existed the semi-periphery, which was

[5] Marcuse, H., 'One-Dimensional Man: Studies in the Ideology of Advanced Industrial Society', (London: Routledge, 1964).
[6] Gramsci, A., 'Notes on Italian History', in 'Selections from the Prison Notebooks', (New York: International Publishers, 1971).
[7] Wallerstein, I., 'The modern World System I: Capitalist Agriculture and the Origins of the European World-Economy in the Sixteenth Century', (New York and London: Academic Press, 1974).

neither developed for it was dependent on the core, nor was underdeveloped for it was industrialized to certain extent.

2. Critique of Clinical Trials

Progress in the life sciences have opened up the port of leading happier, healthier and longer lives, nonetheless there are problems and ethical issues that it carries through. In 2014, the total global pharmaceutical R&D spending was $142 billion.[8] Due to the profit to be gained from the sick in the core countries, pharmaceutical companies have ignored the suffering of the peripheral. At the moment, most of the companies "lack…interest in less lucrative markets and illnesses," [9] and rather invent drug and/or therapies for illnesses such as obesity, even though the peripheral participation in the clinical trials that is conducted by core-based companies cannot be underestimated. Moreover, as the drug consumption in the core nations have skyrocketed,[10] companies are offshoring to 'drug-naïve' countries because the trial results may be biased by the other drugs in the biological system.[11]

There are a lot of studies carried out on the relation between periphery countries and bioethics and/or medical research, however not enough is done with all the available and exceeding resources the world has to prevent death, ailment and suffering. Some critics correctly argue that there is a correlation between bioethics' blindness to the poor and the negative health outcome produced as a result and as such, bioethics needs to be reborn. Bioethics "serves to guide action in an important way through 'limiting the scope of actual decisionmaking to 'safe issues', or what has been called 'non-decision making' –and by narrowing the scope of debate by referring to a certain range of established procedures and/or abstract, universal principles –so-called 'principlism'."[12]As will be discussed later, the theories behind bioethics is carefully crafted to serve the interests of the ones who benefit from the money that exploitation brings. Kaye, for example, contends that "the primary aim of most commercial research is not to promote the health of society, but to develop research plans that will bring in profits for shareholders and investors. While it is anticipated that there will be long-term benefits to humanity as a whole from conducting research in population collections, many of the short-term benefits, such as intellectual property rights and profits will flow to the private company involved."[13]

Free-market economy heartens the use of everything, including individuals and health-care to its maximum benefit. It was not long ago where medicaldom was a charity, its purpose was to serve the community. For the periphery countries also have to benefit from the offshoring of clinical trials, where those States have become minions at the expense of their own people. At

[8] Statista, 'Total global pharmaceutical spending on research and development from 2006 to 2020 (in billion U.S. dollars)'. Retrieved from: http://www.statista.com/statistics/309466/global-r-and-d-expenditure-for-pharmaceuticals/ <accessed on 14/06/2015>.
[9] Styhre, A., 'Organisations and the Bioeconomy: The Management and Commodification of the Life Sciences', (London: Routledge, 2012), 29.
[10] There are other reasons such as weaker regulations in the peripheral, low-cost, etc. for offshoring.
[11] Styhre, A., 'Knowledge Sharing in Professions: Roles and Identity in Expert Communities', (Gower Publishing, Ltd. 2012), 86.
[12] Petersen, A., 'The Politics of Bioethics', (London and New York: Routledge, 2011), 6.
[13] Kaye, J., 'Abandoning Informed Consent: The Case of Genetic Research in Population Collections', in Tutton, R., Corrigan, O., (eds), 'Genetic Databases: Socio-Ethical Issues in the Collection and Use of DNA', (London: Routledge, 2004),125-6.

this point, Marx needs to be revisited. David Harvey argues that neoliberalism[14] was a class project aiming to restore the power to the capitalist class, and mainly to the corporate elites.[15]

Neo-liberalism must be taken in the context of its historical process. Economy and politics were not always unipolar. It is a project that the global capitalist elites developed to dominate the market. For instance, the welfare system restricts the power of the capitalists, it was neo-liberalism that was thrown at the Irish, once declared its independency. In the periphery, Africa, Asia, Latin-America or in Europe –Spain, Greece and Turkey –serves as examples of this project once the working class clashes with the capitalist class. Miliband, writing in the 1980s, expands the subjects of the class struggle.[16] It is not owners of means of production versus workers anymore –the struggle is now between the dominant class comprised of the capitalist elite and the state elite against the working class who are not only industrial workers. Going back to its historical process, Harvey argues that the Great Depression took a good hit at the capitalist class in the U.S. and globally consequently leading to a world-wide critique and scepticism of the free market economy.[17] Thus Keynesian economics was adopted which provided a more prominent role to the State in economics until the 1970s. Harvey provided in *A Brief History of Privatisation* a memo received by the US Chamber of Commerce from Lewis Powell in 1971, in which he advised American businesses to fight back against the "criticism of and opposition to the US free enterprise system". Further unlike Marx's initial model, Miliband does not view the State as subordinate to the capitalist class, he views them to be in concert with each other. This research take the view that private corporations and the State cannot be taken separately, however like Althusser asserts, the State is a tool, an organ of domination. Further, one cannot deny the power of the private entities over health, as exemplified from privatised health-care systems and insurances and one cannot assert that this is done for competition, as facts show worldwide, especially in the US, that there is no better health-care at hand.

Accordingly, scientific research has become neoliberal[18], and debates surrounding it is on the rise.[19]Health and treatments cannot be considered as a commodity to be sold and as a social right simultaneously. Health and medicine needs to be, supposed to be as well as provided by law for everyone.

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[14] Neoliberalism is "a theory of political economic practices that proposes that human well-being can best be advanced by liberating individual entrepreneurial freedoms and skills within an institutional framework characterized by strong private property rights, free markets, and free trades" Harvey, D., 'A Brief History of Privatisation', (New York: Oxford University Press, 2005), 2.

[15] Ibid.

[16] Miliband, R., 'Divided societies: Class Struggle in Contemporary Capitalism', (Oxford: Oxford University Press, 1989).

[17] Green, D., 'Silent revolution: The rise and crisis of market economics in Latin America', (New York: Monthly Review Press, 2003) and Harvey, D., 'A Brief History of Privatisation', (New York: Oxford University Press, 2005).

[18] Atkinson-Grosjean, J., 'Public Science, Private Interests: Culture and Commerce in Canada's Networks of Centres of Excellence' (Ontario: University of Toronto Press 2006); Canaan, J.E. & Wesley, S., (eds.), 'Structure and Agency in the Neoliberal University', (London: Routledge, 2008); and Slaughter, S. & Rhoades, G., 'Academic Capitalism and the New Economy: Markets, State, and Higher Education', (Baltimore: John Hopkins University Press, 2004).

[19] Abraham, J., & Ballinger, R., 'The Neoliberal Regulatory State, Industry Interests, and the Ideological Penetration of Scientific Knowledge', (2012) Science, Technology, & Human Values 443; Fisher, J.A., 'Medical Research for Hire: The Political Economy of Pharmaceutical Clinical Trials', (New Brunswick, NJ: Rutgers University Press, 2009); Rebecca, L., Mirowski, P. & Randalls, S., 'Introduction: STS and Neoliberal Science', (2010) Social Studies of Science 659; Mirowski, P., 'Science-Mart: Privatizing American Science', (Cambridge: Harvard University Press, 2011); and Kelly, M., Kleinman, D.L., David J.H. & Scott F.S., 'Science and Neoliberal Globalization', (2011) Theory and Society 505.

Cooper makes a rightful assertion by associating "Fordist industrial production [to] the mobilisation of a mass of unskilled, docile bodies in the service of a highly standardised, reproducible experiment, owed as much to the time and motion studies of Taylorism as any other sector of mass production"[20]. She further avers that human participants are not protected as exhaustively as its worker counterparts, with the former, with few exceptions, entrapped in the law of privacy, namely tort law, creating a contract out of informed consent, unlike the latter whose protection are covered under their wage contract.[21]

3. Bioethics

> In contemporary society and culture –post-industrial society, postmodern culture –the question of the legitimation of knowledge is formulated in different terms. The grand narrative has lost its credibility, regardless of what mode of unification it uses, regardless of whether it is a speculative narrative or a narrative of emancipation. [22]

In this section the main principles of bioethics, ethical standards for the peripheral and a critique of bioethics will be provided. To begin with it, it is important to note that bioethics starts with the simple thought that an individual is free, autonomous and possesses inherent dignity. Traditionally, a distinction was made between sentient beings and non-sentient beings. Moral status was only attributed to those beings with an intrinsic worth and those falling outside was not granted moral or legal protection. Aristotle and Thomas Aquinas did not grant animals a moral status, hence legitimising the brutal and unjust treatment of them. This perception of animals is also evident from the animal hunts in the Coliseum between the 2nd century B.C.E. and the 6th century C.E. as a *panem et circenses* (literally translated as bread and circuses) meaning for the enjoyment of the public. Kant also did not grant animals a moral status however he cautioned that the brutal treatment of them can lead to the brutalisation of humans, thus called for a proper treatment. This traditional line of thinking is anthropocentric and speciesist. It also important that until recently, the only beings given the status of 'human' were white male.

However, bioethics as we know it is a recent phenomenon and at the start, it was seen as a discipline similar to medical ethics. The sub-groups animal ethics and environmental ethics developed later on. It is generally asserted that bioethics' genealogy can be traced back to publication of two articles; the first by Potter in *Bioethics, the Science of Survival*[23] in 1970 in which he argues for the need of regarding bioethics as a world-wide movement, and the second is by Callahan *Bioethics as a Discipline*[24] in 1973 in which he calls for bioethics to be established as a new academic discipline. However, Sass claims that Fritz Jahr, a German theologian, used the term *Bio-Ethik* (which translates into English as Bio-Ethics) in three articles that he published in 1927, 1928 and 1934.[25] Jahr contended for a new approach to the

[20] Cooper, M., 'Trial by Accident: Tort Law, Industrial Risks and the History of Medical Experiment' in Kelly, A.H. & Geissler, P.W. (eds.) 'The Value of Transnational Medical Research: Labour, Participation and Care', (London: Routledge, 2012), 110.
[21] Ibid, 110-11.
[22] Lyotard, J.F., 'The Postmodern Condition', (UK: Manchester University Press, 1984), 37.
[23] Potter, V.R., 'Bioethics: The Science of Survival', (1970) Perspectives in Biology and Medicine, 127.
[24] Callahan, D., 'Bioethics as a Discipline', (1973) Hastings Centre Studies, 66.
[25] Sass, H.-M., ‚Fritz Jahr's Bioethischer Imperativ. 80 Jahre Bioethik in Deutschland von 1927 bis 2007', (2007) Bochum: Zentrum für Medizinische Ethik.

environment and humans: "Respect every living being, in principle, as an end in itself and treat it accordingly wherever it is possible"[26]. Moreover, Fletcher's[27] and Ramsey's[28] books (1954 and 1970 respectively) supported the flourishment of the debate on hard ethical issues in medicine. The first two centres to operate in medical ethics were the Institute of Society, Ethics, and the Life Sciences created in 1969 (the Hastings Centre) and the Joseph and Rose Kennedy Centre for the Study of Human Reproduction and Bioethics created in 1971. These two institutions also published academic journals; the Hastings Centre Report and the Kennedy Institute of Ethics Journal.

Many also attribute the term 'bioethics' to André Hellegers of University of Georgetown during the time he founded the Kennedy Institute for the Study of Human Reproduction and Ethics where the concept he coined became the title of the Institute's Centre for Bioethics. The principlist school, which will be discussed shortly, took its cue from this initiative.[29]

Finally, an analysis of power relations must be considered to fully understand the concept of bioethics in the 21st century. And going in parallel with the underlying hypotheses of this thesis; there needs to be a discussion of 'non-mainstream' bioethics.

3.1 Principles of Bioethics

3.1.1 Hippocrates

Ethics deals with the questions of what is right and wrong in human behaviour. The focus of medical ethics is the relation between patient and physician; the right and wrong in the behaviour of physicians. The notion of medical ethics finds its origin, at least as commonly asserted, to the Hippocratic Oath in 500 B.C.E., even though medical ethics was first referred to by Thomas Percival in 1803.[30] Moreover, as Kuhse and Singer asserts, its history is much older dating back to tribal societies, where they had "more or less well-articulated values that directed the provision of health care by shamans, exorcists, witches, sorcerers, and priests, as well as by midwives, bonesetters, and herbalists."[31] Medical ethics is also attributed to the Code of Hammurabi in 1750 B.C.E. Its first codification was during the Ostrogothic kingdom in Italy. Later, Ishaq ibn Ali al-Ruhawi, a 9th century Arab physician from Urfa, Turkey wrote the '*Practical Ethics of the Physician'* (Arabic: أدب الطبيب ,Adab al-Tabib).

Hippocratic Oath has been modified many times,[32] without alteration to the five elements that are drawn from the Oath:[33]

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[26] Jahr, F.,'Bio-Ethik. Eine Umschau über die ethischen Beziehungen des Menschen zu Tier und 1, Pflanze', (1927) Kosmos. Handweiser für Naturfreunde,1, 4.

[27] Fletcher, J., 'Morals and Medicine: The Moral Problems of the Patient's Right to Know the Truth, Contraception, Artificial Insemination, Sterilization, Euthanasia', (Boston: Beacon Press, 1954).

[28] Ramsey, P., 'The Patient as Person: Explorations in Medical Ethics', (New Haven: Yale University Press, 1970).

[29] Diniz, D. Guilhem, D., 'O que é Bioética', (Brasiliense 2002), 10-20, 11.

[30] Percival, T., 'Medical Ethics: Or a Code of Institutes and Precepts, Adapted to the Professional Conduct of Physicians and Surgeons', (London, Johnson & Bickerstaff, 1803).

[31] Kuhse, H. & Singer, P., 'A Companion to Bioethics', (Oxford: Wiley-Blackwell, 2009)., 4.

[32] For example, the Oath of Lasagna, the Prayer of Maimonides and the Reinstatement of Hippocratic Oath.

[33] Kuhse and Singer provide that: "In various ethical frameworks, some of these obligations appear as principles, others as rules; some as primary and fundamental, others as secondary and derivative." Kuhse, H. & Singer, P., 68.

1. Beneficence;
2. Non-maleficence;
3. Autonomy;
4. Justice; and
5. Confidentiality.

Beneficence and justice are included in the Hippocratic Oath under the phrase: "I will apply dietetic measures for the benefit of the sick according to my ability and judgment; I will keep them from harm and injustice"[34] (Greek: διαιτήμασί τε χρήσομαι ἐπ' ὠφελείῃ καμνόντων κατὰ δύναμιν καὶ κρίσιν ἐμὴν, ἐπὶ δηλήσει δὲ καὶ ἀδικίῃ εἴρξειν). Confidentiality is deducted from: "What I may see or hear in the course of the treatment or even outside of the treatment in regard to the life of men, which on no account one must spread abroad, I will keep to myself, holding such things shameful to be spoken about"[35] (Greek: ἃ δ' ἂν ἐν θεραπείῃ ἢ ἴδω, ἢ ἀκούσω, ἢ καὶ ἄνευ θεραπηΐης κατὰ βίον ἀνθρώπων, ἃ μὴ χρή ποτε ἐκλαλέεσθαι ἔξω, σιγήσομαι, ἄῤῥητα ἡγεύμενος εἶναι τὰ τοιαῦτα). Non-maleficence is derived from '*Of the Epidemics'*: "The physician must...have two special objects in view with regard to disease, namely, to do good or to do no harm"[36] (Greek: ασκέειν, περί τα νουσήματα, δύο, ωφελέειν ή μη βλάπτειν). A simplification of it is the latin maxim: "First, do no harm" (Latin: primum, non nocere).

The Hippocratic model of medical ethics is paternalistic. The physician wants the best for his/her patient but deems himself/herself to be better in the decision-making process with regards to the patient's well-being; thus the established the supremacy of the physician. However, with the adoption of the UDHR, this has changed. The basic principles concerning patient rights are: the right to medical care of good quality, the right to information concerning own health, the right to freedom of choice, the right of self-determination, the right to confidentiality, the right to information, the right to health education, and the right to dignity. Further, in the physician-patient relationship the upsurge of autonomy can be interpreted as a counteraction to paternalism in healthcare.[37]There are many cultural issues in medical ethics that a 'margin of appreciation' or 'deference' is left for the national governments or courts; for instance abortion, euthanasia or IVF.

3.1.2 Principlism

Beauchamp and Childress have developed the most utilised approach in bioethics (or medical ethics) and continued to refine their approach.[38] The two systemised bioethical approach by the articulation of four principles in no particular order that denotes to primacy of any:[39]

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[34] Edelstein, L., 'The Hippocratic Oath: Text, Translation, and Interpretation', (Baltimore: The Johns Hopkins Press, 1943).
[35] Ibid.
[36]Hippocrates, 'Of the Epidemics', (Book I, Section II, para. V) Retrieved from: http://classics.mit.edu/Hippocrates/epidemics.1.i.html <accessed on 01/02/2015>
[37] Internet Encyclopaedia of Philosophy, 'Bioethics', Retrieved from: http://www.iep.utm.edu/bioethic/ <accessed on 04/03/2015>.
[38] Beauchamp, T.L. & Childress, J.F., 'Principles of Biomedical Ethics', (6th ed., Oxford University Press 2009).
[39] "…our order of presentation does not imply that this principle has priority over all other principles. A misguided criticism of our account is that the principle of respect for autonomy overrides all other moral considerations. This we firmly deny." Ibid, 57.

1. Principle of respect for autonomy;
2. Principle of non-maleficence;
3. Principle of beneficence; and
4. Principle of justice.

The first principle, autonomy rests on the presumption that one has to be autonomous in order to exercise free will and it is through the participants' voluntary informed consent that they are demonstrated to be autonomous.[40] The second, beneficence is built upon the principal that the trial is in the interests of public good.[41] The third one, non-malevolence, presupposes that the damage to the involved parties will be minimized and the last principle is fairness.[42] These four principles come together as the building blocks of the ethos for clinical trials to satisfy the conditions of "civic equality" and "reciprocity of the social contract".[43]

It must be noted, nonetheless, that the hegemonic essence of the principlist theory has become a matter of concern among the critics since the early 1990s. [44] Those involved in transformative bioethics too have been protesting such universal ethos, pointing out various socio-economic phenomena including, but not limited to, global financial order, social exclusion, unequal distribution of scientific and technological means as well as that of consumer goods necessary to survive. [45] In fact, to develop a more egalitarian perspective requires an in-depth reflection on a long list of complex contradictions most of which are extrinsic to the first world reality.

Beauchamp and Childress define non-maleficence as "the principle that we ought not to inflict evil or harm on others".[46] Non-maleficence and beneficence is usually taken together, however the distinction is crucial, as Beauchamp and Childress observe, "the obligation not to injure others intuitively seems more stringent than the obligation to rescue them."[47] Beneficence is "best understood as a variant of the philosophical principle of utility, which stipulates that right actions are those that have a preponderance of good consequences over bad. Beneficence therefore requires that research projects maximize potential benefits and minimize the risk of harm."[48] Schwartz contends that the principles of beneficence and non-maleficence are "prima facie duties, which is to say, their violation is ethically wrong unless it is justified by another prima facie duty"[49].

This approach put forward by Beauchamp and Childress even though widely acknowledged and used, does not go uncontested. The three significant protestations are: "first, the lack of ethical guidance because there is no master principle in cases of conflict among the principles; secondly, the problem of bias concerning the universal principles in cross-cultural contexts;

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[40] Rán, M. & Carlos Augusto Peixoto Júnior, C.A.P., 'Vulnerability and bare life: bioethics and biopolitics today', (4 June 2007). Retrieved from: http://www.scielo.br/scielo.php?pid=S0034-89102007000500020&script=sci_arttext&tlng=en <accessed on 11/03/2015>.
[41] Ibid.
[42] Ibid.
[43] Ibid.
[44] Ibid.
[45] Ibid.
[46] Beauchamp, T.L. & Childress, J.F. (n 40) 152.
[47] Ibid.
[48] Kuhse, H. & Singer, P. (n 33) 461.
[49] Schwartz, G., 'Hippocrates Revisited', 31. Retrieved from: https://www.einstein.yu.edu/uploadedFiles/EJBM/21Schwartz33.pdf <accessed on 11/03/2015>.

and thirdly, the objection that the four-principle approach is a mere checklist of considerations and so methodologically unsound."[50]

3.1.3 Principles in the Belmont Report

The Report lists two moral arguments as fundamentals of the respect for persons, first of which is that the persons have to be treated as "autonomous agents" and the other is that those with "diminished autonomy" have to be under protection.[51] The respect for persons, thus, is comprised of two distinct requirements, the former being the "requirement to acknowledge autonomy" and the latter the "requirement to protect" the persons with diminished autonomy. Although the concept of "beneficence" is commonly identified with an indefinite number of indeterminate acts that are of voluntary kind and are performed out of kindness, the Report strives to redefine beneficence with specific reference to obligation.[52] Beneficence, the Report asserts, is expressed only when (1) no harm is intended and (2) the potential good is maximized whereas any actual harm is minimized.[53] When it comes to the notion of "justice", the Report makes mention of an array of interrelated issues of social concern such as "fairness in distribution," "what is deserved," and "equals ought to be treated equally." It is the opinion of the Report that it is when a person is harnessed with an unduly burden or is denied a benefit without a sound reason that the "injustice" comes to being." The report abstains from defending any particular theory of justice; yet, it attempts to demonstrate the relevance of justice to research centred around human subjects, referring to the infamous clinical work such as Tuskegee syphilis study and Nazi experiments on concentration camp prisoners.[54]

3.1.4 Other Ethical Standards

The rise in the number of international biomedical clinical trials is raising concern about the ethics of such research. Koski and Nightingale argue that, "ethics and science are not separable — a given study must conform to ethical standards or it should not be performed, and it must be scientifically sound or it cannot be ethical. The use of a good research design and adherence to sound ethical principles should result in the conduct of research that is valid, reliable, and ethically acceptable in any country."[55] Given that the ethical standards exist and must be adhered to conduct a clinical research on human participants, why are so many individuals are abused and capitalised on? Elliott and Abadie suggest that unethical research is "endemic".[56] An example of ethical standards is offered by Emanuel and his colleagues, where they synthesised traditional codes and rules and the literature to particularise the ethical requirements of clinical research, which are:[57]

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[50] Internet Encyclopaedia of Philosophy (n 39).
[51] The National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, 'The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research,' (18 April 1979). Retrieved from: http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html <accessed on 11/03/205>.
[52] Ibid.
[53] Ibid.
[54] Ibid.
[55] Koski, G., & Nightingale, S.L., 'Research involving human subjects in developing countries', (2001) New England Journal of Medicine 136.
[56]Elliott, C. & Abadie, R., 'Exploiting a Research Underclass in Phase I Clinical Trials' (2009) N New England Journal of Medicine 389.
[57] Emanuel, E.J., Wendler, D. & Grady, C., 'What Makes Clinical Research Ethical?' (2000) JAMA 2701, 2701.

1. Social or scientific value;[58]
2. Scientific validity;[59]
3. Fair subject selection;[60]
4. Favourable risk-benefit ratio;[61]
5. Independent review;[62]
6. Informed consent;[63] and
7. Respect for potential and enrolled subjects.[64]

This author is of the view that the four norms offered by Robert Merton, even though not directly related to clinical trials, provide a sound framework for ethics of science. In *The Normative Structure of Science*, he sets out to define the "ethos" of science by referencing to four "institutional imperatives", also known as 'CUDOS', namely:[65]

1. Communism;: "the common ownership of scientific discoveries, according to which scientists give up intellectual property rights in exchange for recognition and esteem.";
2. Universalism: "according to which claims to truth are evaluated in terms of universal or impersonal criteria, and not on the basis of race, class, gender, religion, or nationality";
3. Disinterestedness: "according to which scientists are rewarded for acting in ways that outwardly appear to be selfless"; and
4. Organised scepticism: "all ideas must be tested and are subject to rigorous, structured community scrutiny."

His description on the ethos of science:

> The ethos of science is that affectively toned complex of values and norms which is held to be binding on the man of science. The norms are expressed in the form of

[58] Explanation: "Evaluation of a treatment, intervention or theory that will improve health and well-being or increase knowledge". Justifying ethical value is: "Scarce resources and non-exploitation". Ibid, 2703.
[59] Explanation: "Use of accepted scientific principles and methods, including statistical techniques, to produce reliable and valid data". Justifying ethical value is: "Scarce resources and non-exploitation". Ibid.
[60] Explanation: "Selection of subjects so that stigmatised and vulnerable individuals are not targeted for risky research and the rich and socially powerful not favoured for potentially beneficial research". Justifying ethical value is: "Justice". Ibid.
[61] Explanation: "Minimisation of risks; enhancement of potential benefits; risks to the subject are proportionate to the benefits to the subject and society". Justifying ethical value is: "Nonmaleficence, beneficence and non-exploitation". Ibid.
[62] Explanation: "Review of the design of the research trial, its proposed subject population, and risk-benefit ratio by individuals unaffiliated with the research". Justifying ethical value is: "Public accountability; minimising influence of potential conflicts of interest". Ibid.
[63] Explanation: "Provision of information to subjects about purpose of the research, its procedures, potential risks, benefits, and alternatives, so that the individual understands this information and can make a voluntary decision whether to enrol and continue to participate". Justifying ethical value is: "Respect for subject autonomy". Ibid.
[64] Explanation: "Respect for subjects by: (1) permitting withdrawal from the research; (2) protecting privacy through confidentiality; (3) informing subjects of newly discovered risks or benefits; (4) informing subjects of results of clinical research; and (5) maintaining welfare of subjects. Justifying ethical value is: "Respect for subject autonomy and welfare". Ibid.
[65] Merton, R.K., 'The Normative Structure of Science', (1942). Retrieved from: https://www3.nd.edu/~dhoward1/Merton's%20Norms.pdf <accessed on 14/04/2015>.

> prescriptions, proscriptions, preferences, and permissions. They are legitimatized in terms of institutional values. These imperatives, transmitted by precept and example and reinforced by sanctions are in varying degrees internalized by the scientist, thus fashioning his scientific conscience or, if one prefers the latter-day phrase, his superego. Although the ethos of science has not been codified, it can be inferred from the moral consensus of scientists as expressed in use and wont, in countless writings on the scientific spirit and in moral indignation directed toward contraventions of the ethos.[66]

On the purpose of science, he writes:

> The institutional goal of science is the extension of certified knowledge. The technical methods employed toward this end provide the relevant definition of knowledge: empirically confirmed and logically consistent statements of regularities (which are, in effect, predictions). The institutional imperatives (mores) derive from the goals and the methods. The entire structure of technical and moral norms implements the final objective. The technical norm or empirical evidence, adequate and reliable, is a prerequisite for sustained true prediction; the technical norm of logical consistency, a prerequisite for systematic and valid prediction. The mores of science possess a methodological rationale but they are binding, not only because they are procedurally efficient, but because they are believed right and good. They are moral as well as technical prescriptions.[67]

Uniform care requirement necessitates that all the participants to a research "should receive the level of care they would receive in a developed country." Macklin, calling it "a flawed statement," is highly critical of this universal view: "adhere to this requirement would make it impossible to do research designed to develop treatments for tropical diseases in remote, rural area of developing countries, which lack the facilities of tertiary care hospitals in industrial countries."[68] This position is also stated in *Ethical Aspects of Clinical Research in Developing Countries* as follows:

> [R]esearch activities involving human subjects cannot exclusively be assimilated to an economic activity subject to market rules. On the contrary, in the context of solidarity, regarding health as a public good, rather than a commodity, it needs to be regulated according to fundamental principles. The general approach chosen within this Opinion is that the fundamental ethical rules applied to clinical trials in industrialised countries are to be applicable everywhere. Even if some difficulties may arise in their implementation, a weakening of the standards would be in contradiction to the fundamental principles of human rights and dignity and their universal guarantee and protection.[69]

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[66] Merton, R.K., 'The Sociology of Science: Theoretical and Empirical Investigations', (Chicago and London: University of Chicago Press, 1979), 268-69.
[67] Ibid, 270.
[68] Macklin, R., 'Appropriate Ethical Standards' in Emanuel, E.J., Grady, C.C., Crouch, R.A., Lie, R.K, Miller, F.G. & Wendler, D.D., (eds), 'The Oxford Textbook of Clinical Research Ethics', (New York: Oxford University Press, 2011), 712.
[69] Opinion of the European Group on Ethics in Science and New Technologies to the European Commission, Ethical Aspects of Clinical Research in Developing Countries, No. 14 (4 February 2003), 12.

3.2 Critique of Bioethics

It has been said that bioethics "has become what McKinnie[70] has referred to as an 'affirmative institution: pro-capitalist, pro-technology, and pro-governmental."[71] Furthermore, it is polyphonic and debates on it "take place on the boundary of academic and public political discourse…and that there is no agreement on what exactly bioethics is in the first place."[72] De Vries *et al* characterise it as not being "a monolithic entity" and rather operating with "a single perspective and mode of enquiry, reinforced by a cadre of leaders whose position and expertise are unchallenged –an orthodox professional group capable of enforcing such tight discipline that the 'field' speaks with one voice on all issues."[73] Mainstream bioethics by and large restrain the remit of "actual decision-making to 'safe' issues, or what has been called 'non decision making"[74]. This means that there needs to be an analysis of how and why the discourse used today in bioethics is applied and followed.

Bioethics as a new form of imperialism, is a "political means for the creation of a global moral economy where the trading and exchange of ideas is normalised and legitimated"[75]. It denies the "the diversity of perspectives on the biosciences and emergent biotechnologies and conceal their gender, class and ethnicity biases" [76] serving as "a tool of governance, in helping to engender consent and legitimacy for the development of technologies that involve many uncertainties"[77].

Science and medicine is at the end of the day a social construct, and those who determine it, craft and develop it according to their benefit. Thus, since bioethics is West-centric and especially a product of Anglo-American values rather than universal ones,[78] it is the core nations that set the standards and criteria. Thus not only they come up with the laws and policies but they also come up with rationale to justify them which are the interests that benefit themselves. As well as being an ideology, bioethics function in a top-down method. To illustrate the careful construction of bioethics narrative that serves the interests of the dominant elite, Carson and Burns gives the example of a national commission shaping the

[70] McKinnie, M., 'A Sympathy for Art: Sentimental Economic of New Labour Arts Policy', in Johnson, R. & Steinberg, D.L., (eds), 'Blairism and the War of Persuasion: Labour's Passive Revolution', (London: Lawrence and Wishart, 2004).
[71] Murray, S.J. & Holmes, D., 'Introduction: Towards a Critical Bioethics', in Murray, S.J. & Holmes, D., (eds) 'Critical Interventions in the Ethics of Health Care: Challenging the Principle of Autonomy in Bioethics', (Surrey: Ashgate, 2009), 2.
[72] Düwell, M., 'Bioethics: Methods, Theories, Domains', (London: Routledge 2014), 2.
[73] De Vries, R., Turner, L., Orfali, K. & Bosk., C., 'Social Science and Bioethics. The Way Forward', in 'The View from Here: Social Science and Bioethics', (Oxford: Blackwell, 2007), me2.
[74] Bachrach, P. & Baratz, M.S., 'Decisions and Nondecisions: An Analytical Framework' (1963) American Political Science Review 632, 632.
[75] Salter, B. & Salter, C., 'Bioethics and the Global Moral Economy: The Cultural Politics of Human Embryonic Stem Cell Science', (2007) Science, Technology and Human Values 554, 555.
[76] Petersen, A., 'The Politics of Bioethics', (London and New York: Routledge, 2011), 6.
[77] Ibid, 2.
[78]Christakis, N., 'Ethics are local. Engaging cross-cultural variations in the ethics for clinical research' (1992) Social Science & Medicine, 1079.; Durante, C., 'Bioethics in a pluralistic society: bioethical methodology in lieu of moral diversity' (2009) Medical Health Care and Philosophy, 35.; Hedgecoe, A., ' Critical bioethics: beyond the social science critique of applied ethics' (2004) Bioethics, 120.; Levine, R., 'Informed consent: some challenges to the universal validity of the Western model' (1991) Law, Medicine, and Health Care, 207.; Marshall, P., 'Anthropology and bioethics' (1992) Medical Anthropological Quarterly, 152.; Turner, L., 'Bioethics in a multicultural word: medicine and morality in pluralistic settings' (2003) Health Care Analysis, 99.

conduct of foetal research.[79] They assert that if the commission has been comprised of representatives from Operation Rescue, a delegate from the Pope of Rome, a libertarian, a pro-choice advocate, a committed atheist, a Maoist Communist, etc., no agreement will be reached. Thus, representatives who can collaborate are chosen and the issues are selected in such a way that they will not trigger endless debate but rather encourage the meeting of minds:

> Consensus and agreement are constructed not just through the careful direction of debate and reflection by whoever chairs the meetings, but by the prior selection of participants. Consensus and agreement are manufactured by shaping the structure of the debates that will take place and by determining who will participate in them.[80]

With hand-picked representatives come expected results and there is born a bioethics that the dominant class desires. The ideas behind this particular bioethics as Marx would say, is vital to control the society and shaping it accordingly as those ideas operate as "the ideal expression of the dominant material relationships, the dominant material relationships grasped as idea; hence the relationships which make the one class the ruling one, there the ideas of its dominance"[81]. The rationality adopted is simulation, where the State utilises the bioethicists to make sure that the people perceive it as beneficial to them. The narrative of the dominant elite to the people is delivered by the "conceptive ideologists, who make the perfecting of the illusion of the class about itself their chief source of livelihood"[82]. Petersen claims that the history of bioethics have constrained the thinking about bioethics and its representation have assisted as an ideology fulfilling certain goals, i.e. the goals of the dominant elite:

> The ways in which bioethics ideas are employed to justify certain lines of action or to legitimise inaction, and the related expertise that is utilised in the effort to realise desired outcomes…how bioethics ideas may help reinforce dominant relations of power a detrimentally affect or potentially affect people's health and wellbeing by drawing attention away from substantive questions, such as whether particular technologies were should be developed at all.[83]

4. Law on Research Participant Protection

This chapter will chiefly provide an analysis and overview of how sources of quasi-legal and ethical guidelines address human experimentation and argue that law as it currently stands has failed to protect participants.

The most infamous research experiments conducted on humans by the Nazis, the Human Radiation Experiments or the Tuskegee Syphilis Study (1932-1972) should be adequate to demonstrate that human cruelty and ruthlessness coupled with scientific knowledge know no limit. As answers to 'never again' cries, documents such as the Nuremberg Code (1947) and

[79] Carson, R.A. & Burns, C.R. (eds.), 'Philosophy of Medicine and Bioethics: A Twenty-Year Retrospective and Critical Appraisal', (New York: Kluwer Academic Publishers, 2002).
[80] Ibid 94.
[81] Marx, K. & Engels, F., 'The German Ideology', (New York: International Publishers, 1964), 39.
[82] Ibid 40.
[83] Petersen, A., 'The Politics of Bioethics', (London and New York: Routledge, 2011), 3.

the Declaration of Helsinki (1964) were produced to act as guidelines for physicians and researchers. Further, theories such as Kant's Categorical Imperative: "Act in such a way that you treat humanity, whether in your own person or in the person of any other, never merely as a means to an end, but always at the same time as an end"[84] is being also used as a safeguard from the abusive human experimentation. The guidelines are not satisfactory, for instance the Tuskegee Syphilis Study (Belmont Report 1979)[85] was committed in spite of the Nuremberg Code and the Declaration of Helsinki. It is very dangerous to assume that the measures are adequate to guarantee ethical behaviour in research.

There are myriad codes of practices, declarations and regulatory guidelines that aim to ensure that research on human is ethical and participants are protected. Every nation who permits research on human has governing principles regulating it. Nuremberg Trials attained unprecedented attention on experimentation on human subjects and its ethics, however, the discussion of medical ethics have started long ago. The milestone for the protection of human subjects is the Hippocratic Oath which provided for an ethical responsibility on the part of the physician to the patient, even though standards for research in the international context can be said to emerge with the Nuremberg Code. Despite the long history of medical ethics and the recent declaration and guidelines the individuals were exploited and the abusers went unpunished. The inadequacy of the ethical guidelines lies with their birth, as most are the result of a specific event, for instance the Nuremberg Code was the product of the Nazi fascism and Tuskegee Syphilis Experiment was the main cause for drafting the Belmont Report.

Generally, the guidelines concentration lies with procedural safeguards of informed consent and independent review of research ethics committees because these "leave paper trails that can subsequently be audited."[86] Grady and his colleagues refer to the existing guidance's as "deficiencias", for they are "neither comprehensive nor systematic."[87] More importantly, they do not provide justifications for their assertions, implying that the guidance is "either self-evident or beyond debate."

The bioethics literature and the regulations that emerged are "never again" cries and a form of dealing with the past. However, many oppose the mainstream bioethics for it enforces Eurocentric/US-centric individual rights, especially the principle of autonomy, moreover, the imposition of individual rights only makes it easier to exploit the people. In the midst of all, the important issue is missed, it is not only the peripheral countries that get exploited (it is the most exploited due to its economic weakness) and the most pressing reason is bioethics, just like any power and profit apparatus, is used to the benefit of the rich.

4.1 The Nuremberg Code

[84] Kant, I., 'Groundwork for the Metaphysics of Morals', Gregor, M. & Timmermann, J. (trans. & eds.) (New York: Cambridge University Press, 2012).
[85]The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979). The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Belmont Conference Centre.
[86] Emanuel, E.J., Wendler, D. & Grady, C.C., 'An Ethical Framework for Biomedical Research', in Emanuel, E.J., Grady, C.C., Crouch, R.A., Lie, R.K, Miller, F.G. & Wendler, D.D. (eds), 'The Oxford Textbook of Clinical Research Ethics', (New York: Oxford University Press, 2011), 123.
[87] Ibid.

During the *U.S.A. v Karl Brandt et al*[88], a case part of the Nuremberg War Crimes Trials (1946-7), one of the defendants argued that there was not any law to determine as to what constitutes legal experimentation on humans. Consequently, in the verdict ruled on 19 August 1947, ten ethical principles were laid out which is now the Nuremberg Code. Accordingly, Nazi physicians were found guilty of crimes against humanity under those principles.[89] The main preach of the Code is the requirement of informed consent and absence of coercion.

For Katz, the Code:

> …is a remarkable document. Never before in the history of human experimentation, and never since, has any code or any regulation of research declared in such relentless and uncompromising a fashion that the psychological integrity of research subjects must be protected absolutely.[90]

A year after the Nuremberg Code, the Universal Declaration of Human Rights (UDHR) was adopted. Baker claims that the "the details revealed daily at Nuremberg gave content to the rights recognized by Articles 4 through 20 of the Declaration". According to him, until the adoption of the UDHR, "'the nature of 'human rights' was left unspecified"[91].

Articles 1 and 2 of the UDHR require respect for human dignity and equality. The Code has a human rights approach and thus the articles aforementioned in particular overlaps with medical ethics. It also provides for right to life[92], the prohibition of torture or cruel, inhuman or degrading treatment or punishment[93], requires non-discrimination[94], freedom from arbitrary interference with privacy[95], progressive realisation of the human right to a standard of living adequate for health and medical care[96] and the right to share in scientific advancement and its benefits[97].

4.2 The Declaration of Geneva

A year after World Medical Association (WMA) was founded, it issued the Declaration of Geneva in 1948[98], serving as a modern reinstatement of the Hippocratic Oath, clarified for the twentieth century.

4.3 The Declaration of Helsinki

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[88] U.S. Military Tribunal Nuremberg, Judgment of 19 July 1947. Also known as the Doctors' Trial.
[89] Annas, J.G. & Grodin, M.A., 'The Nazi Doctors and the Nuremberg Code: Human Rights in Human Experimentation', (New York: Oxford University Press, 1992).
[90] Katz, J., 'The Consent Principle of the Nuremberg Code: its Significance The and Now', in Annas, G.J. & Grodin, M.A. (eds), The Nazi Doctors and the Nuremberg Code, (New York: Oxford University Press, 1992), 227-239, 227.
[91] Baker, R., Bioethics and Human Rights: A Historical Perspective', Cambridge Quarterly of Healthcare Ethics (2001), 10, 241, 242.
[92] Article 3
[93] Article 5
[94] Article 7
[95] Article 12
[96] Article 25
[97] Article 27
[98] Adopted by the 2nd General Assembly of the World Medical Association, Geneva, Switzerland, September 1948 and amended by the: 22nd World Medical Assembly, Sydney, Australia, August 1968; 35th World Medical Assembly, Venice, Italy, October 1983; 46th WMA General Assembly, Stockholm, Sweden, September 1994; 170th Council Session, Divonne-les-Bains, France, May 2005 (Editorial Revision); 173rd Council Session, Divonne-les-Bains, France, May 2006.

The Declaration of Helsinki (DoH) was promulgated at the WMA meeting in Helsinki in 1964 and revised seven times between 1975 and 2013.[99] It provides an ethical guideline for clinical research focusing on the protection of participants. Nearly all ethical guidelines have their genesis in DoH.[100]It bears characteristics of traditional medical ethics: "The health of my patient will be my first consideration".[101] The DoH is an important document in the history of research ethics as the first significant effort of the medical community to regulate research itself. It forms the basis of most subsequent documents and is now widely accepted as the cornerstone document of human research ethics.

In comparison with previous documents, the DoH weighed more heavily on furthering "scientific knowledge and to help suffering humanity" than on individual human subjects. As such, the utmost principle in the Code (namely Article 1) was disregarded, accordingly the declaration permits research without the free and informed consent of the human subject, allowing research on children (specifically vaccines) and on non-competent or 'captive' people.[102] This shift, by some is said to be due to the changing political and social dynamics.

Major expansions were implemented in its 2000 edition, the protection of research subjects retained with the need for public health emphasised. This systematic approach of the DoH departed away from the responsibility of individual physicians and researchers and led to for instance the introduction of the concept of independent ethics committees which translated into the institutional review board system in the U.S.[103] One of the most notable aspect was its distinction between 'therapeutic' and 'non-therapeutic' research. The purpose of research in DoH 2000 is to benefit the future patients rather it's intended to benefit the research subject.[104] It seems as though this edition has sided away from traditional medical ethics and favoured commercialisation of health.

The most recent revision of DoH, unprecedentedly required compensation and treatment for injuries suffered during the course of the research.[105] The amendments that seem to be implemented incessantly undermine its authority.[106] The declaration assigns its mandate to be physicians in Article 2 which weakens the scope of protection it lends to the research subjects. Instead WMA should extend its mandate to all those involved in research.

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[99] Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and amended by the: 29th WMA General Assembly, Tokyo, Japan, October 1975; 35th WMA General Assembly, Venice, Italy, October 1983; 41st WMA General Assembly, Hong Kong, September 1989; 48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996; 52nd WMA General Assembly, Edinburgh, Scotland, October 2000; 53rd WMA General Assembly, Washington DC, USA, October 2002 (Note of Clarification added); 55th WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clarification added); 59th WMA General Assembly, Seoul, Republic of Korea, October 2008; 64th WMA General Assembly, Fortaleza, Brazil, October 2013.

[100] For example, the Council for International Organisations of Medical Science (CIOMS), the International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002) ; the International Conference on Harmonisation –Good Clinical Practices (ICH-GCP) Guidelines (1996), the Amended Schedule Y; and the Indian Council of Medical Research (ICMR) Ethical Guidelines for Biomedical Research on Human Participants (2006).

[101] Article 3.

[102] Lederer, S.E., 'Research without Borders: The Origins of the Declaration of Helsinki', in: Schmidt, U. & Frewer, A., 'History and Theory of Human Experimentation: The Declaration of Helsinki and Modern Medical Ethics', (Stuttgart: Franz Steiner Verlag, 2007), 155-6.

[103] Emanuel E.J., Crouch R.A., Arras J.D., Moreno J.D., Grady C. 'Ethical and Regulatory aspects of clinical research: readings and commentary', (Baltimore: Johns Hopkins University Press, 2003), 7–20.

[104] "Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research" (paragraph 19).

[105] Article 15

[106] Emanuel, E.J., 'Reconsidering the Declaration of Helsinki', (2013) Lancet, 381.

4.4 International Ethical Guidelines for Biomedical Research Involving Human Subjects

CIOMS, an international, non-profit and non-governmental organisation was formed jointly by the WHO and UNESCO in 1949 to represent and serve the interests of the biomedical community. Proposed International Ethical Guidelines for Biomedical Research involving Human Subjects was promulgated in 1982, updated in 1990s which resulted in two sets of guidelines: International Guidelines for Ethical Review of Epidemiological Studies (1991) and International Ethical Guidelines for Biomedical Research Involving Human Subjects (1993). The latter, as revised in 2002, is an attempt to establish ethical principles concerning biomedical research on human subjects in the peripheral countries. The primary objective of the guidelines is to alleviate the gaps in the Code and the DoH, especially to tailor it to take into regard cultural differences in ethical standards while undertaking cross-cultural research. It further assists those countries to apply the principles set out in DoH.

Contrary to DoH, "it may be ethically acceptable to use an alternative comparator –placebo or no treatment,"[107] however, it does recognise that the use of a comparator could result in exploitation of poor and disadvantaged populations.[108] The commentary under Guideline 8: Research involving persons in underdeveloped communities, acknowledges that "individuals and families in such communities are liable to exploitation for various reasons".[109] Furthermore, it calls for an oversight entity; review by an ethical review committee.[110] In Guideline 15: Obligations of sponsoring and host countries, an oversight entity is also called for in the host country.[111]

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[107] Placebo may be used:

- when there is no established effective intervention;
- when withholding an established effective intervention would expose subjects to, at most, temporary discomfort or delay in relief of symptoms;
- when use of an established effective intervention as comparator would not yield scientifically reliable results and use of placebo would not add any risk of serious or irreversible harm to the subjects.

Guideline 11.

[108] The objection rests on three arguments:

- Placebo control could expose research subjects to risk of serious or irreversible harm when the use of an established effective intervention as comparator could avoid the risk.
- Not all scientific experts agree about conditions under which an established effective intervention used as a comparator would not yield scientifically reliable results.
- An economic reason for the unavailability of an established effective intervention cannot justify a placebo-controlled study in a country of limited resources when it would be unethical to conduct a study with the same design in a population with general access to the effective intervention outside the study.

Commentary on Guideline 11.

[109] "To guard against exploitation of individuals and families in socially and economically exploitable communities, sponsors and investigators who wish to conduct in such communities research that could be carried out reasonably well in developed communities must satisfy their national or local ethical review committees, and in the case of externally sponsored research the appropriate ethical review committee in the host country, that the research would not be exploitative. The reason for choosing an underdeveloped community should be made explicit." Council for International Organizations of Medical Sciences, International Ethical Guidelines for Biomedical Research Involving Human Subjects (1993), 25.

[110] Ibid.

[111] "When externally sponsored research is initiated and financed by an industrial sponsor such as a pharmaceutical company, it is in the interest of the host country to require that the research proposal be submitted with the comments of a responsible authority of the initiating country, such as a health administration, research council, or academy of medicine or science." Ibid, 44.

Macklin, in *Bioethics, Vulnerability and Protection* posed: "What makes individuals, groups or countries vulnerable?" CIOMS define vulnerable people as "those […] who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength or other needed attributes to protect their own interests".[112] Further, it elaborates on the groups that could be considered as vulnerable:

- Members of a hierarchical group such as students, medical staff, pharmaceutical company employees and law enforcement agents;
- Elderly;
- Residents of nursing homes, people receiving welfare benefits or social assistance and other poor people and the unemployed, patients in emergency rooms, some ethnic and racial minority groups, homeless persons, nomads, refugees or displaced persons, prisoners, patients with incurable disease, individuals who are politically powerless, and members of communities unfamiliar with modern medical concepts; and
- Persons who have serious, potentially disabling or life-threatening diseases.

4.5 ICH-GCP

A joint effort between the U.S., EU and Japan, the International Conference on Harmonisation, was formed in 1990, to create international standards on drugs in order to facilitate international trade. The Good Clinical Practice Guidelines set out standards for overseeing the protection of research participants and contain the responsibilities of the institutional review boards. Clinical trials should be conducted according to the ICH-GCP hence the standardisation for clinical trial of drugs.

There exists a set of numerous research standards all of which aims to assure that the data employed and results reported by a clinical study are valid, and that the participants' rights and wellbeing, along with their integrity and confidentiality, are protected. The GCPs are bound with the doctrines set by the DoH.

Dr. Gomes identified the requirements in the DoH that were not present in ICH-GCP:[113]

1. Investigators must disclose funding, sponsors and any conflicts of interest to IRBs (Ethics Review Committees) and Informed Consent to study participants;
2. Study design is publicly disclosed & results published - hence clinical trial registries;
3. Research to benefit, and be responsive to health needs of, populations in which research is done;
4. Restricted use of placebo controls even where there is no practical access – e.g. IV drugs, costly drugs in developing countries;
5. Post-trial commitment to treatment access; and

[112] Council for International Organizations of Medical Sciences in collaboration with the World Health Organisation, 'International Ethical Guidelines for Biomedical Research Involving Human Subjects', (Geneva 2002), Commentary on Guideline 13.

[113] Gomes, M., 'Guidelines and Documents on the Ethical Aspects of Clinical Trials', World Health Organisation-Tropical Disease Research, Retrieved from http://www.unicri.it/special_topics/clinical_research/ethics_human_rights/training_tanzania/Gomes%20-%20Ethics%20Guidelines.pdf <accessed on 21/06/2015>.

6. Authors to report results accurately, and make public negative findings.

4.6 The Joint American and European Charter on Medical Professionalism

The American Board of Internal Medicine Foundation, the American College of Physicians – American Society of Internal Medicine Foundation and the European Federation of Internal Medicine established the Medical Professionalism Project and their effort "Medical Professionalism in the New Millennium: A Physician Charter"[114] was published in 2002 quickly becoming popular for providing the cannons of medical professionalism. Despite, compliance with the Charter has not been accomplished.

The document was issued as a response to deal with the corporate agenda and to tackle profit-based health care markets. It rests on three main principles:

1. The primacy of patient welfare;
2. Patient autonomy; and
3. Social justice.

4.7 European Context

The Additional Protocol[115] to the Council of Europe's Convention on Human Rights and Biomedicine (1997)[116] focused on biomedical research especially on human experimentation. Article 5 provides that "research on human beings may only be undertaken if there is no alternative of comparable effectives". Good clinical practice is defined under Article 1(2) of the European Union Directive[117], however it is not applicable to non-interventional trials:

> A set of internationally recognised ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects. Compliance with this good practice provides assurance that the rights, safety and well-being of trial subjects are protected, and that the results of the clinical trial are credible.

4.8 Human Rights

Human rights and ethics have been complementary and as evident from UDHR, human rights and bioethics are also in harmony. Jonathan Mann claims that there is a lean towards human rights in 'global bioethics'.[118] Some scholars argue that in the future, human rights discourse could dominate bioethics.[119] There are three human rights instruments that provide protection, mirroring the medical ethics documents: The Universal Declaration of Human Rights (UDHR), the International Covenant on Civil and Political Rights and the International Covenant on Economic, Cultural and Social Rights (ICESCR).

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[114] ABIM Foundation, ACP-ASIM Foundation, European Federation of Internal Medicine, 'Medical professionalism in the new millennium: a physician charter', Ann Intern Med. 2002; 136:243-246.
[115] Additional Protocol to the Convention on Human Rights and Biomedicine Concerning Biomedical Research (2005).
[116] Council of Europe, Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (1997).
[117] European Parliament and the Council of Europe Directive 2001/20/EC of 4 April 2001 relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.
[118] Mann, J., 'Medicine and Public Health, Ethics and Human Rights', Hastings Centre Report (1997) 27/6: 6-13
[119] Faunce, T.A., 'Will International Human Rights Subsume Medical Ethics? Intersections in the UNESCO Universal Bioethics Declaration', Journal of Medical Ethics (2005) Vol. 31, 173-178.

"Human rights strongly support the medical ethics principle of informed consent, and medical ethics supports the human rights concept of the right to health. Human rights are universal and as such apply to all humans; they also articulate governmental obligations, and as such, focus on states. Health is jurisdictions, and is the result of a political process in a particular country –which may or may not be the result of a country signing a particular treaty, obligating it to implement certain domestic law. Bioethics, especially its subcategory of medical ethics, defines the obligations of physicians when treating patients, and can also define a physician's obligations when working for the state (usually seen as the domain of human rights)."

There is a huge scope for the use of human rights in relation to research on human subjects. They are interconnected, for example, commenting on the Universal Declaration on the Human Genome and Human Rights, Salter and Jones express that behind it "lies the rise of bioethics as a political and, to the extent that it advocates a coherent system of values, ideological phenomenon capable of acting in opposition to the economic regulatory dynamic". For Annas, "the disciplines of bioethics, health law, and human rights are…all members of the broad human rights community….". Gostin agrees, but laments that "bioethics scholars are only beginning to go beyond individual interests to explore the fundamental importance of a population's health and well-being." Baker says that "originally, the principles of bioethics were a means for protecting human rights, but through a historical accident bioethical principles came to be considered as fundamental".

European Convention on Human Rights and Biomedicine has been constrained by its limited ratification.[120] Its scope includes matters such as equitable access to health care (article 3); consent (chapter II); private life and right to information (chapter III); the human genome (chapter IV); scientific research (chapter V); and organ and tissue removal from living donors for transplantation (chapter VI).

Many international and national instruments contain provisions for the protection of the right to life, the prohibition on torture and the positive obligation upon the states to realise the 'human right to health'[121]. Article 7 of the ICCPR provides that "no one shall be subjected without his free consent to medical or scientific experimentation". Under general comment 20, the United Nations human rights committee has construed this to require "special protections" for individuals "under any form of detention or imprisonment" or for those in hospitals due to mental illness whether it be on the ground of necessity or involuntarily.[122]

Under Article 38(1) of the Statute of the International Court of Justice, for instance Universal Declaration on the Human Genome and Human Rights is not a binding instrument.

Adorno furthermore argues that human rights are best understood as a result of a consensus on justifications. The agreed set of human rights may not be the result of wide reflective equilibrium, but they are nevertheless agreed:

> The global success of the human rights movement in contemporary society is probably due to the fact that a practical agreement about the rights that should be respected is perfectly compatible with theoretical disagreement on their ultimate

[120] Council of Europe, Convention for the protection of human rights and the dignity of human beings with regard to the application of biology and medicine. 1997 ETS 164.
[121] Toebes, B., 'Towards an Improved Understanding of the International Human Right to Health' (1999) Human Rights Quarterly, 671.
[122] Supra 120.

foundation. The Universal Declaration of Human Rights of 1948 is the best example of this phenomenon, because it was drafted by representatives of particularly diverse, even opposed, ideologies. Upon this strong legislative foundation has been built an extensive network of human rights mechanisms designed to develop international standards, monitor their implementation and investigate violations of human rights.[123]

Adopting a human rights approach come with important benefits:

1. "states voluntarily agree to be bound by human rights, and such rights therefore have undisputed normative force;
2. that human rights jurisprudence provides an interpretative system for determining the scope and meaning of human rights; and
3. that specific institutions (e.g. the European Court of Human Rights) can provide authoritative interpretations with legal force."[124]

South Africa, is a good example where human rights and social justice language have been "endogenised in bioethics, which is showing great promise for overturning the cycle of suffering especially from HIV/AIDS pandemic.[125]

5. U.S. Practices & Current Mechanism for Accountability

The U.S., as the epitome of commercialisation and neoliberalisation, has the number one spot in the globalisation of clinical trials. Adashi noted that, "… the unabated globalization of biomedical research has reached a tipping point whereupon over half of all clinical trials registered with ClinicalTrials.gov are conducted beyond the confines of the continental U.S."[126]

5.1 How "we the people" became "we the market"[127]

Tyfield argue that "science become increasingly legitimated and prioritised on predominantly (if never exclusively) economic grounds," and is evinced by the privatisation of research funding in the US.[128] Private entities' monopoly on science can be traced back to the two catalyst events that took place in 1980 for the enhancement of investment in biotech industry generally and especially for gene patenting. The U.S. Supreme Court ruled (by a 5-4 ruling)

[123] Teays, W., Gordon, J.S. & Renteln, A. (eds.), 'Global Bioethics and Human Rights: Contemporary Issues', (USA: Rowman & Littlefield, 2014), 48.
[124] Ibid.
[125] Pleasants, G.J. 'Bioethics and Human Rights: A Problem, a Proposal, and an Achievement' (Boston College Electronic Thesis or Dissertation 2007). Retrieved from http://dlib.bc.edu/islandora/object/bc-ir:102436/datastream/PDF/view 7. <accessed on 17/06/2015>.
[126] Adashi E.Y. 'International Human Subject Research: Taking Stock in the Wake of the Guatemala Affair' (2011) Contemp Clin Trials, 605–607.
[127] Dickenson, D., 'Me Medicine vs. We Medicine: Reclaiming Biotechnology for the Common Good', (New York: Columbia University Press, 2013), 184.
[128] "Private funding of scientific research in the US has grown 3.8 times in real terms (8.7 times in nominal terms) since 1980 against increases of federal government funding of 1.5 times (and 3.5 times respectively). As a result, private funding of total research and development (R&D) has grown to 65-70 per cent of total national R&D expenditure in the decade from 1998-2008 from just under 50 per cent in 1980 (National Science Foundation 2010)." Tyfield, D., 'The Economic of Science: A Critical Realist Overview. Volume 1: Illustrations and Philosophical Preliminaries', (London: Routledge, 2011), 6.

for the patentability of life forms in the controversial decision of *Diamond v Chakrabarty*[129] and the U.S. Congress, passing the Bayh-Dole Act,[130] enabled federally funded research patentable, in other words provided for the vesting of the intellectual property over a federally funded research in the organisation that conducted the research. Prior to the enactment of Bayh-Dole, the state owned approximately 30,000 federally funded research patents.[131] As they were not commercialised, in the language of de Soto, the patents were "dead capital".[132] The Act lured private investments thus commercialised the assets;[133] number of gene patents granted increased from 12 in 1970s to 143 in the 1980s,[134] from 1,175 patents between 1981 to 1995 to over 25,000 by 2000,[135] turning the patents into "live capital".[136] To put it in another way, the Congress wanted to remedy "the failure of discoveries to enter the marketplace", Krimsky citing Mirowski: "To allow wealth from discoveries to be realised, the Act turned the principle of capitalism on its head: 'private risk yields private loss or gain' became 'public risk yields public loss or private gain'."[137] Burdening the commercialisation of science solely on Bayh-Dole Act is not right, the Act "was just one component in a whole range of roughly simultaneous reforms 'being engineered into corporations, the government, and the universities' all calculated to instigate the marketplace of ideas throughout the entire culture".[138] A factor to keep in mind is the launch of the Human Genome Project by the National Institutes of Health (NIH) in 1990. Accordingly, the reason for the increase in the number of patents may well be tripartite: the Bayh-Dole Act, *Chakrabarty* decision and the Human Genome Project. However, commercialisation and especially patenting has not been chiefly driven by the scientific community, the underlying force are the political and economic profit.[139]As a consequence of the Act, the fuel of research departments of universities and healthcare institutions is

[129] 447 US 303 (1980). Chakrabarty sought to patent a genetically modified bacterium. The Court ruled that the patent sought was an invention and thereby patent eligible: "[Chakrabarty's] micro-organism plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity 'having a distinctive name, character, use.'". Ibid, 309–10. The Court further stated that: "Here…the patentee has produced a new bacterium with markedly different characteristics from any found in nature…His discovery is not nature's handiwork, but his own; accordingly, it is patentable subject matter under § 101." Ibid, 308–10. Chief Justice Warren Burger held that "the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions."

[130] The Act was passed to cultivate "the commercialisation and allocation of rights in inventions resulting from federally sponsored research and development." Moore, C., 'Killing the Bayh-Dole Act's Golden Goose' (2006) Tulane Journal of Technology & Intellectual Property 153, 153.

[131] Ibid 156.

[132] De Soto, H., 'Dead Capital and the Poor' (2001) SAIS Review, 17.

[133] Rai, A. & Eisenberg, R., 'Bayh-Dole Reform and the Progress of Biomedicine', (2003) American Scientist, 52.

[134] Kean, S., 'The Human Genome (Patent) Project', (2011) Science, 531.

[135] Williams-Jones, B., 'History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing', (2002) Health L.J., 126.

[136] De Soto, H., 'Dead Capital and the Poor', 21 SAIS Review 1 (2001), 17.

[137] Krimsky, S. 'A Neoliberal Economics of Science', American Scientist (July-August 2011), Book Review of Mirowski, P., 'Science-Mart: Privatising American Science', (Cambridge: Harvard University Press, 2011). Retrieved from http://www.tufts.edu/~skrimsky/PDF/Review%20Science-Mart.PDF <accessed on 26/04/2015>.

[138] Ibid.

[139] Molecular biologists were always attempting to discover genes for medical interests, the potential for academic advancement and status. They did not think that they would be able to patent genes. Roberts, L., 'Controversial from the Start', (2001) Science ,1185-1186.

dominantly commercial interest, [140] potentially fortifying conflict of interests between individuals and institutions.[141]

5.2 FDA's Oversight on Foreign Clinical Trials

In 2010, two years after FDA amended its foreign clinical trial regulations, the Office of Inspection General issued *Challenged to the FDA's Ability to Monitor and Inspect Foreign Clinical Trials.*[142] In reporting on the data submitted in 2008 fiscal year, it wrote that 80% of approved marketing applications for drugs and biologics included data from foreign clinical trials.[143] In the same year, 78% of the participants were non-U.S. citizens and over 58% of the clinical trials' site were outside of the U.S. Furthermore, only 0.7% of foreign clinical trials were inspected by the FDA despite the fact that this is not the first time that OIG has expressed concern about lack of FDA oversight on foreign clinical trials. [144]

To market a drug or biologic in the U.S., the companies must firstly submit a marketing application to the FDA.[145] The Federal Food, Drug, and Cosmetic Act necessitates all new investigational drugs to undergo clinical trials on human subjects which demonstrate the safety and efficacy of these products prior to their approval for marketing.[146] Phase III trial results are the main decisive factor for FDA to approve of the marketing of a new drug.[147] An Investigational New Drug Application (IND) must be submitted to the FDA by any sponsor intending to conduct clinical trials in the U.S. When a sponsor submits an IND to FDA, the FDA's authority to oversee clinical trials begin.[148] IND provides the option of conducting clinical trials outside of the U.S. to the sponsors however the interstate commerce laws does not encapsulate to foreign counties thus rendering the IND procedure unnecessary.[149][150] Nevertheless, the sponsors can submit the results of foreign conducted clinical trial under an IND to reinforce a current IND. Good Clinical Practice must be adhered to if a sponsor wants to submit data from foreign conducted clinical trials not conducted under an IND.[151]

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[140] See, for example, Martin, J.B. & Kasper, D.L., 'In Whose Best Interest? Breaching the Academic-Industrial Wall', (2000) The New England Journal of Medicine and Mukherjee, S., 'Why Public Science Can 'I Really Be Public', New Republic, (8 May 2000), 14.
[141] Kelch, R.P., 'Maintaining the Public Trust in Clinical Research', (2002) The New England Journal of Medicine, 285.
[142] Office of Inspector General, Department of Health & Human Services, OEI-01-08-00510, Challenges to FDA's Ability to Monitor and Inspect and Inspect Foreign Clinical Trials (2010). Retrieved from http://oig.hhs.gov/oei/reports/oei-01-08-00510.pdf <accessed on 16/06/2015>.
[143] Ibid.
[144] See Office of Inspector Gen. Dep't of Health & Human. Servs., OEI-01-00-00190, The Globalisation of Clinical Trials: A Growing Challenge in Protecting Human Subjects, (2001); Office of Inspector Gen., Dep't of Health & HuM. Servs., OEI-0 1-06-00160, The Food and Drug Administration's Oversight of Clinical Trials (2007)
[145] 21 C.F.R. § 314.50 (2011) (In relation to New Drug Application (NDA) for drugs); 21 C.F.R. § 601.2 (2011) (In relation to Biologic Licensing Application (BLA) for a biologic).
[146] Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (Amended 21 U.S.C. §§ 301-399a (2004)).
[147] Ourso, A., 'Can the FDA Improve Oversight of Foreign Clinical Trials: Closing the Information Gap and Moving Towards a Globalized Regulatory Scheme' (2012) Annals of Health Law, 493, 498.
[148] Ibid, 499.
[149] Ibid.
[150] Ibid.
[151] Ibid.

Problems foreign clinical trials face, as put by Wilson, are:[152]

1. The FDA's lack of knowledge of most FCTs because they are not being conducted under an IND;
2. The minimal experience and few resources that many of the countries being used to host these studies can devote to the regulation such studies require;
3. The human rights violations resulting from inadequate informed consent136 and exploitation of vulnerable populations; and
4. The concerns over data validity as a result of lax oversight and conflicts of interest.

5.3 Case-Law: Holding U.S.-based Companies Accountable

"[I]t takes injury, scandal, or sustained patient advocacy to hold trial sponsors accountable…"[153]

Alien Tort Statute (ATS), [154] passed in 1789, is a 226-year-old statute that has been interpreted to allow alien plaintiffs to bring a suit in the U.S. courts for violations customary international law (CIL).[155] In other words, the U.S. courts have jurisdiction to hear matters alleging violations of the law of nations which is the U.S. colloquial for CIL. [156] It can also be applied to private actors if the conduct in question is egregious. In *Kadic v Karadzic*,[157] the court held that: "Individuals may be held liable for offenses against international law, such as piracy, war crimes, and genocide,"[158] nevertheless, it is usually held that only states can be in breach of international, thus the claimant must demonstrate that the defendant "acted in concert with" the state.[159] Alien's action for tort is provided in § 28: "The district courts shall have original jurisdiction of any civil action by an alien for a tort only, committed in violation of the law of nations or a treaty of the United States."[160] Thus, the statute as well as permitting the incorporation of international law into U.S. law, sanctions a private right of action for damages when the violation amounts to a tort. The limited scope of the ATS has been highlighted in many decisions. Furthermore, the application of the statute is ambiguous, contaminating the remedies and legal protections foreign clinical trial participants may seek.

To avail of the statute, the claimant must meet three requirements:[161]

1. Claimants must be an alien;

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[152] Wilson B. 'Clinical Studies Conducted Outside of the United Sates and Their Role in the Food and Drug Administration' (2013) University of Pennsylvania Journal of International Law, 163.
[153] Petryna, A., 'When Experiments Travel: Clinical Trials and the Global Search for Human Subjects', (Princeton, NJ: Princeton University Press 2009), 137.
[154] 28 U.S.C. § 1350.
[155] It has been inactive for a very long time thus leading the Second Circuit to describe it as "kind of legal Lohengrin". 13D Wright, C.A., Miller, A.R. et al., 'Federal Practice and Procedure', § 3585 (3d ed. 2009).
[156] Sosa v Alvarez-Machain, 542 U.S. 692, 720, 723 (2004).
[157] 70 F.3d 232, 239–40 (2d Cir. 1995).
[158] Ibid, 239-40. The court citing Restatement (Third) of Foreign Relations Laws of the U.S. (1986).
[159] Kadic v Karadzic, 70 F.3d 232, 239 (2d Cir. 1995), cert. denied, 116 U.S. 2524 (1996) The offences violating the law of nations as applied to private persons is limited, includes slavery, war crimes, piracy and genocide; see also Abdullahi, 562 F.3d, 188. The Court quoting Kadic, 70 F.3d, 232: "A private individual will be held liable under the ATS if he 'acted in concert with' the state, i.e., 'under color of law.'".
[160] 28 U.S.C. § 1350 (2006).
13D Wright, C.A., Miller, A.R. et al., 'Federal Practice and Procedure', § 3585 (3d ed. 2009).
[161] Sosa v Alvarez-Machain, 542 U.S. 692, 720, 723 (2004).

2. Claimants must have a claim sounding in tort; and
3. The party alleging violation under the ATS must establish that "the tort committed in violation of the law of nations or a treaty of the United States."

5.3.1 Flores v S. Peru Copper Core

In *Flores v S. Peru Copper Core,*[162] the claim was brought against U.S. mining company by the representatives of a Peruvian miner who was killed.[163] The plaintiffs relied upon Article 6(1) of the ICCPR[164], however the Second Circuit excluded the ICCPR on the basis that it was not a self-executing treaty and that it was "insufficiently definite" to be defined as a standard under the customary international law. [165] The Court provided the customary international to be "those rules that States universally abide by, or accede to, out of a sense of legal obligation and mutual concern,"[166] and immediately limiting it by holding that "in determining what offenses violate customary international law, courts must proceed with extraordinary care and restraint."[167] Moreover, the Court ruled that "shocking or egregious" conduct does not constitute a basis for a claim under ATS unless it actually breached customary international law.
[168]

5.3.2 Sosa v Alvarez-Machain

Within the scope of actuality, victims of human rights violations such as torture has invoked ATS against the offending states.[169] *Sosa v Alvarez-Machain,*[170] was such a case, where the plaintiff, a Mexican citizen, claimed that the U.S. Drug Enforcement Agency (DEA) had arbitrarily arrested him and brought him to the U.S. to stand trial.[171] Both the U.S. District Court for the Central District of California and the U.S. Court of Appeals for the Ninth Circuit have ruled that matter could be tried in the U.S. jurisdiction and there was a cause of action.[172] However, the Supreme Court reversed the decision and held that Sosa did not have a right of action because he did not satisfy the third requirement, namely, that the tort in question was not a violation of the law of nations.[173] Justice Souter reasoned that Sosa's claim of arbitrary arrest did not "rest on a norm of international character accepted by the civilised world and defined with a specificity comparable to the features of the recognised 18th-century paradigms we have recognised."[174] Moreover, it is essential that the courts be

[162] Flores v. S. Peru Copper Corp., 343 F.3d 140 (2d Cir. 2003).
[163] Ibid, 143-44.
[164] "Every human being has the inherent right to life."
[165] Ibid, 163–64.
[166] Ibid, 154.
[167] Ibid.
[168] Ibid, 159.
[169] See, for example, Filartiga v Pena-Irala, 630 F.2d 876 (2d Cir. 1980). Torture was found to be a violation of international law; Tel-Oren v Libyan Arab Republic, 726 F.2d 774 (D.C. Cir. 1984) The court ruled that the PLO attack on bus does not come within the jurisdiction; Doe I v Unocal Corp., 395 F.3d 932 (9th Cir. 2002), vacated en banc, 403 F.3d 708 (9th Cir. 2005).
[170] 542 U.S. 692 (2004).
[171] Ibid, 695.
[172] Ibid, 699.
[173] Ibid, 697.
[174] Ibid, 725.

"particularly wary of impinging on the discretion of the Legislative and Executive Branches in managing foreign affairs."[175]

In relation to the Universal Declaration of Human Rights that was relied upon by Sosa, the Court declared that it "[d]oes not of its own force impose obligations as a matter of international law,"[176] as well as not creating "obligations enforceable in the federal courts"[177] on its own. Similarly, ICCPR was not seen as constituting international law thus, the Court did not allow the use of it: "[ICCPR] does bind the United States as a matter of international law, the United States ratified the [it] on the express understanding that it was not self-executing and so did not itself create obligations enforceable in the federal courts."[178]

The court was tentative to not to get involved with foreign policy, Justice Scalia stated that the "federal courts" should not be in the business of "recognizing any further international norms as judicially enforceable today, absent further congressional action," and concluded by reiterating "that federal courts have no authority to derive 'general' common law."[179]Nevertheless, the Court left the "door ajar," only to let in "a narrow class of international norms", and recapping that it will be "subject to vigilant door keeping."[180]

Thus the Court expressly signalled that it will interpret the scope of international law very restrictively, thus making it difficult for a litigant to have a standing under the ATS.

5.3.3 Kiobel v Dutch Petroleum

Kiobel v Dutch Petroleum,[181] the Nigerian plaintiffs who were members of an activist group that opposed to oil exploration in their village in the Ogoni Region due to the environmental effects it causes.[182] They brought a class action lawsuit against the companies Royal Dutch Petroleum and Shell Transport and Trading, on the basis that the defendant aided and abetted the Nigerian government in violating human rights containing, arbitrary arrest, detention, extrajudicial killings, forced exile, torture and property destruction.[183]The Supreme Court did not consider whether an actionable claim was present under the ATS but rather posed "whether a claim may reach conduct occurring in the territory of a foreign sovereign."[184] Chief Justice Roberts writing for the majority opinion brought in the "touch and concern" rule which significantly departed from the decades of ATS interpretation. In doing so, he cited the presumption against extraterritorial application, stating that "[w]hen a statute gives no clear indication of an extraterritorial application, it has none,"[185] to apply it to the ATS. The Chief Justice further emphasised that where "all the relevant conduct [takes] place

[175] Ibid, 727.
[176] Ibid, 735.
[177] Ibid, 734-35.
[178] Ibid. See further, ibid 728. The court noted that "the Senate expressly declined to give the federal courts the task of interpreting and applying international human rights law, as when its ratification of the [ICCPR] declared that the substantive provisions of the document were not self-executing."
[179] Ibid, 735.
[180] Ibid.
[181] Kiobel v Royal Dutch Petroleum Co., 621 F.3d 111, (2d Cir. 2011).
[182] Ibid, 123.
[183] Ibid.
[184] Kiobel v. Royal Dutch Petroleum Co., 133 S. Ct. 1659, 1664 (2013).
[185] Morrison v. Nat'l Austl. Bank Ltd., 130 S. Ct. 2869, 2878 (2010).

outside the United States", then "mere corporate presence" did not "touch and concern" the U.S. "with sufficient force to displace the presumption against extraterritorial application."[186]

The "touch and concern" standard depends on whether the plaintiff, defendant or conduct is foreign. Many lower courts have applied Chief Justice Robert's majority opinion and ended up with different conclusions as to the applicability of the ATS.[187] This decision faced a lot of criticism for the legal scholars and human rights advocates due to its highly restrictive approach.

5.3.4 Trovan Litigation

In the first *Abdullahi v Pfizer*[188] litigation, the surviving victims of the Kano-Trovan study filed a lawsuit on the foot of ATS alleging that Pfizer violated the law of nations as directed by the Code, the DoH, the ICCPR[189] and "other norms of international law." The main claims of the plaintiffs were: (1) the defendant did not obtain informed consent from the children clinical trial participants, their parent or guardians; (2) the experiment "exposed them to cruel, inhuman and degrading treatment"[190];(3) the defendant did not inform that they had the right to refuse the treatment and that Doctors Without Borders was within the same facility, administering a free, safe and effective treatment[191]; and (4) the defendant did not follow its own research protocol.[192] The District Court dismissed the case on the basis of *forum non coveniens*.[193] *Forum non conveniens* required Pfizer "to demonstrate that an adequate alternative exists,"[194] and for the court to determine between private and public interest when "the balance of convenience tilts strongly in favour of trial in the foreign forum."[195] Further, the court recognised that the remedy provided by another forum can in "rare" situations be

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[186] Kiobel, 133 S. Ct., 1669.

[187] Compare, e.g., Sexual Minorities Uganda v. Lively, 2013 WL 4130756, at *15 (D. Mass. Aug. 14, 2013) (quoting Kiobel, 133 S. Ct. at 1669) ("Given that Defendant is a United States citizen living in this country and that the claims against him 'touch and concern the territory of the United States . . . with sufficient force to displace the presumption against extraterritoriality,' a cause of action is appropriate under the ATS."), with Al Shimari v. CACI Int'l, Inc., 2013 WL 3229720, at *9 (E.D. Va. June 25, 2013) (noting that "Plaintiffs' reading of Kiobel is a fair one," because Kiobel's 'touch and concern' language may be interpreted in many ways but nevertheless dismissing the plaintiffs' claims); see also Doe v. Exxon-Mobil Corp., 2013 WL 3970103 (D.C. Cir. July 26, 2013).

[188] Abdullahi v Pfizer,Inc.,2002 WL 31082956, 1. (Abdullahi I). The plaintiffs claimed that "Pfizer acted as a de facto state actor because it conducted the Trovan study with the assistance of the Nigerian government and government employees from IDH and Aminu Teaching Hospital." Ibid, 5.

[189] Article 7

[190] Joe Stephens, 'Suit Accuses Pfizer of Rights Violations', Washington Post, (30 August 2001), A9. Retrieved from: https://www.washingtonpost.com/archive/politics/2001/08/30/suit-accuses-pfizer-of-rights-violations/a11b32b2-8044-4bc6-b299-df1270ecda88/ <accessed on 13/04/2015>.

[191] Abdullahi I, 2002 WL 31082956, 2.

[192] Abdullahi I, 2002 WL 31082956, 2.

[193] "The district court found *forum non conveniens* based on the following considerations: (1) Nigeria provided an adequate alternative forum; (2) Pfizer was already defending a lawsuit in Nigeria based on the same conduct [Zango v Pfizer Int'l, Inc., Case No. FHC/K/CS/204/2001(Nigeria).]; (3) the presumption that a plaintiff's choice of forum is convenient is weaker when the plaintiff is foreign; (4) Nigerian courts should be able to apply international law as effectively as U.S. courts; (5) Nigeria has a strong interest in the litigation; and (6) most of the documents and witnesses necessary for trial are located in Nigeria." Wollensack, A.F., 'Closing the Constant Garden: The Regulation and Responsibility of U.S. Pharmaceutical Companies Doing Research on Human Subjects in Developing Nations', 6 Wash. U. Global Stud. L. R.747, (2007) 756, 759.
See, also, Ibid, 6–12.

[194] Ibid, 6.

[195] Ibid. Quoting R. Maganlal & Co. v M.G. Chem. Co., 942 F.2d 164, 167 (2d Cir. 1991).

substandard thus the forum might prove to be inadequate.[196] The court is forbidden to dismiss the case to an alternative forum, if the plaintiffs can demonstrate that under the forum, they are "highly unlikely to obtain basic justice therein"[197] or "conditions are so ever as to call the adequacy of the forum into doubt."[198] Accordingly, the court found Nigeria to be a better forum.

The plaintiffs appealed to the U.S. Court of Appeals for the Second Circuit. In Abdullahi II,[199] the court reversed the District Court's decision and ruled that the plaintiffs could bring a claim against Pfizer on the foot of ATS: "prohibition on nonconsensual medical experimentation on human beings constituted a universally accepted norm of customary international law, and consequently an alleged violation."[200] It held that informed consent violation was an international norm under the *Sosa* decision.[201] Nearly after 15 years, Pfizer settled the charges, both criminal and civil, with the Nigerian authorities by signing a $75 million settlement agreement subject to a confidentiality clause.[202] In addition, Pfizer agreed to pay a maximum of $175,000 per child.[203]

5.3.5 Implications of the Decisions

The decisions are construed restrictively and are highly unsatisfactory for it is an obstruction for violated claimants looking to sue the transnational companies. Likewise, ATS is not an ideal route for compensating the victims of clinical trials for it has a narrow application and the U.S. courts are reluctant to expand it.[204] In addition, it is not "an effective tool to change the behaviour of American pharmaceutical companies conducting clinical trials abroad."[205] The U.S. should strengthen federal law in favour of clinical trial participant -litigants and enhance FDA oversight over foreign trials. Furthermore, Coyne argues that the U.S. should establish civil and criminal penalties akin to Foreign Corrupt Practice Act,[206] and calls for the amendment of the ATS in order to enable foreign clinical trial participants to file a suit "when the underlying action is capable of regulation by the FDA."[207]

To sum up, in the cases mentioned above, all of the claimants' allegations of breach of rights were founded upon international documents that deserve upholding from a court of law.

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[196] Ibid, 8. The court quoting Piper Aircraft Co. v Reyno, 454 U.S. 235, 254 n.22 (1981).
[197] Ibid. The court quoting Cabiri v Assasie-Gyimah, 921 F. Supp. 1189, 1199 (S.D.N.Y. 1996).
[198] Ibid. The court quoting Leon v Million Air, Inc., 251 F.3d 1305, 1312 (11th Cir. 2001). ; Abdullahi v Pfizer, Inc., 77 F. App'x 48, 52 (2d Cir. 2003), (Abdullahi II), "[I]f the plaintiff shows that conditions in the foreign forum plainly demonstrate that plaintiffs are highly unlikely to obtain basic justice therein, a defendant's *forum non conveniens* motion must be denied."
[199] Abdullahi v Pfizer, Inc., 562 F.3d 163 (2nd. Cir. 2009)
[200] Ibid.
[201] Ibid, 187.
[202] Steven W. Postal, et al., A Remedy in Sight: International Clinical Research Regulation in the Wake of Guatemala and Nigeria, 6 PITT. J. ENVTL PUB. HEALTH L. 1 (2011), 21.
[203] Farbstein, S. 'Breaking News: settlement in Abdullahi v. Pfizer (Human Rights at Harvard Law, 23 February 2011). Retrieved from http://hrp.law.harvard.edu/alien-tort-statute/breaking-news-settlement-in-abdullahi-v-pfizer/ <accessed on 18/06/2015>.
[204] Sosa 542 U.S.
[205] Coyne, D. M. 'International Pharmaceutical Mistrials: Existing for the Protection of Foreign Human Subjects and a Proposal for Reform', Boston University International Law Journal, 430. Retrieved from http://www.bu.edu/ilj/files/2014/05/Coyne-finalpdf.pdf <accessed on 04/03/2015>.
[206] Ibid 428.
[207] Ibid 431.

Accordingly, it does not seem very likely that clinical trial participants or their representatives will be well protected under the ATS.

5.4 Offshoring

As of 2000 to April 2015, of the 189,109 trials registered on ClinicalTrials.gov, six percent of the trials were run both in U.S. and outside U.S., thirty-nine percent were run only in the U.S. and forty-five percent were run outside of the U.S.[208] Over the course of nine years, from 1990-1999, the number of host countries for research involving human subjects amplified to twenty-nine to seventy-nine, the largest increased occurred in Russia, Eastern Europe and Latin America.[209]

Offshoring of clinical trials is due to many factors, including lax regulations, low-costs[210] and faster and drug-naïve and general patient recruitment.[211] The industry loses $1.3 million for every day the drug is not commercialised. In the U.S. while 7% of the trials begin as programmed, 78% of the trials cannot meet their deadlines for recruitment and 70 % cannot recruit the number of participants required for to conduct the trial. Approximately less than 50% of the trials either recruit all of the participants required or achieve their recruitment goal without delaying the time allocated for recruitment.[212]

Harvard Business Review wrote that, by offshoring half of its clinical trials to India and South America, an average-sized U.S. pharmaceutical company with 60,000 patients in clinical trials could save $600 million per year.[213] In addition the companies do not bother with overcoming communication difficulties such as "research," "hypothesis," and "randomisation" that leads to the contamination of informed consent. [214]

6. Exploitation & Clinical Trial Practices

[208] 'Trends, Charts and Maps', ClinicalTrials.gov, retrieved from https://www.clinicaltrials.gov/ct2/resources/trends <accessed on 28/04/2015>.
[209] Macklin, R., 'Double Standards in Medical Research in Developing Countries', (Cambridge: Cambridge University Press, 2004), 7.
[210] As Thomas Fogarty states: "[E]merging third-world countries have become pretty popular", especially Latin American countries such Argentina, Brazil, Mexico and Paraguay, "[there] you can find people who are well-trained in their work and do follow-up with patients. It's an affordable process in those places."
Goll, D., 'Clinical Trials Move Overseas to Speed Process, Save Money', Silicon Valley Business Journal, (13 April 2012). Retrieved from http://www.bizjournals.com/sanjose/print-edition/2012/04/13/clinical-trials-move-overseas-to-speed.html?page=all <accessed on 29/04/2015>.
[211]"Patient recruitment is absolutely essential to the success of pharmaceutical research, and consequently patient care, but today nearly 80% of clinical trials fail to meet their enrolment timelines and up to 50% of research sites enrol one or no patients. Not only does this translate into as much as $8m in lost revenue for each day a drug is delayed". 'Clinical Trial Delays: America's Patient Recruitment Dilemma',drugdevelopmet-technology.com, (19 July 2012). Retrieved from http://www.drugdevelopment-technology.com/features/featureclinical-trial-patient-recruitment/ <accessed on 23/04/2015>.
"According to the Tufts Centre for the Study of Drug Development (CSDD), enrolment rates have dropped 20 percent since 2000." Creamer, A. 'Clinical trials on rise, but many lack participants' (The Sacramento Bee, 2 February 2013)
http://www.sacbee.com/news/local/health-and-medicine/article2576521.html#storylink=cpy
[212] Homedes, N. & Ugalde, A., 'Clinical Trials in Latin America: Where Ethics and Business Clash', (Dordrecht: Springer International Publishing 2014), 57.
[213] Garnier, J.P., 'Rebuilding the R&D in Big Pharma' (2008) Harvard Business Review, 68.
[214] Spielman, B. 'Offshoring Experiments, Outsourcing Public Health', in Cohen, I.G., (ed), 'The Globalization of Health Care: Legal and Ethical Challenges', (Oxford: Oxford University Press, 2013), 289.

Moving clinical trials to peripheral with weaker regulations, maximises the profit of the pharmaceutical companies. The cost of developing a new drug in the U.S. which include preliminary research, completing Phase I,II and III trials on clinical trial participants, obtaining investigational new drug (IND) permit by obtaining preliminary approval from the FDA, incur loss.[215] To gain the FDA's new drug application (NDA) approval, there is a requirement of testing on clinical trial participants, which prove to be less costly in those nations. [216] Many U.S.-nationals do not want to be clinical trial participants where many nationals of the periphery enrol in clinical trials as a "healthcare windfall" as this is their chance of receiving healthcare.[217]

It can be argued that the transfer of clinical trials in fact prove to be beneficial for the sick in both U.S. and the sites where the trial is conducted (as they receive drugs and treatment that otherwise would not be available).[218] However, the lax and ineffective regulatory and judicial infrastructure leave the clinical trials participants exploited and where trial-related injury or death is incurred there is very little recourse to compensation or accountability.

6.1 Peripheral Clinical Trials

Global clinical trials are increasing as well as the exploitation of its participants. The root cause of the exploitation is afforded to mainly the double standard that is employed as most of the studies in the peripheral have failed to apply the standards applied in the core nations, leading to regulatory violations and risking the lives of the participants. Typical cases where the concern of exploitation arise are informed consent, clinical equipoise, the use of randomised clinical trials (placebo control and active-controlled trials), and the lack of drug availability in the site that the clinical trial was conducted should the drug be successful.

When discussing exploitation in clinical trials context, many scholars dismiss the descriptive Marxist concept of exploitation and instead adopt a moral one.[219] The morality-driven exploitation cannot fully address the entirety of the adversities that the participants face in the course of the clinical trials. This is due to the fact that morality is a highly relative subject, and various theoretical contentions should be value-free and not be influenced by subjective perspectives, value commitments, community and/or personal bias should not affect the fate of the clinical trial participants. To strike a balance, exploitation should be regarded within the economic realm.

Firstly, two examples of clinical trials will be discussed, following a discussion of payment made to clinical trial participants. Next, brief accounts of morally-driven theories of exploitation will be provided and will conclude by defending the application of Marxist concept of exploitation to clinical trial participants.

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[215] Anderson, C.W. & Zhang, Y.J. 'Security Market Reaction to FDA Fast Track Designations' (2010) , Journal Health Care Fin., 27.
[216] Malinowski, M.J. 'Ethics in a Global Pharmaceutical Environment' (2006), Santa Clara Journal of International Law, 67.
[217] Cekola, J. 'Outsourcing Drug Investigations to India: A Comment on U.S., Indian and International Regulation of Clinical Trials in Cross-Border Pharmaceutical Research' (2007), Northwestern Journal of International Law and Business, 129.
[218] Laughton, A.H. 'Somewhere to Run, Somewhere to Hide? International Regulation of Human Subject Experimentation' (2007) Duke Journal of Comparative and International Law, 202.
[219] Scholars such as Alan Wertheimer, John Lawrence Hill, Jennifer Hawkins and Ruth Sample.

6.2 Randomised Clinical Trials

Interestingly, the general principles of the clinical trials were first laid out by a statistician R.A. Fischer,[220] however, it was Austin Bradford Hill in 1946 published in the British Medical Research Council and it can be referred to as the standard procedures for conducting randomised clinical trials (RCT):

> The significance of this innovation cannot be overstated. Without this shift in the scale of experiment, it would be impossible to envisage the rise of mass biomedicine, mass-market drugs or national health care as distinctively modern enterprises. [221]

Geissler and Kelly, argued that to sophisticate the experimental methods of the RCT, wars, with its "mass mobilisation of regimented bodies and its legal exceptionalism" proved to be ideal.[222] However, when the war was over, the bodies were not as collectively and readily available, thus there emerged the "logistical problem of how to replicate the mobilisation of docile bodies on a smaller scale, without diminishing the scientific validity of their experiments."[223] Kutcher's claim that the treatment of cancer patients as 'proxy soldiers' of Cold War trials and Hornblum's observation of prison-based trials during the 1960s were a hint to the solution of the problem.[224]

6.2.1 AZT Trials

The ACTC (AIDS Clinical Trials Group) 076 Regimen, the AZT (antriretroviral drug zidovudine) treatment reduced the risk a HIV-positive mother would transmit the virus onto her baby was invented in1994. Mother-to-child transmission (MTCT) is the prominent cause of HIV infection in infants in Africa.[225] The treatment per individual, at the time, cost $1,000 which was impossible to purchase in periphery countries.[226] To alleviate the situation, the WHO held a meeting that included no ethicists decided that placebo-controlled trials would be the best and affordable approach.[227] Consequently trials were to be held in 11 periphery countries, however if the interventions worked, the sponsors did not pledge to provide the successful drugs to the populations of those 11 countries. The executive editor of the New England Journal of Medicine, Marcia Angell denouncing the AZT trials, compared it to the Tuskegee Syphilis Experiment.[228] Lurie and Wolfe: "Residents of impoverished, postcolonial countries, the majority of whom are people of colour must be protected from potential

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[220] Marks, H., 'The progress of Experiment', (Cambridge: Cambridge University Press, 1997), 141-147.
[221] Kelly, A.H. & Geissler, P.W. (eds.) 'The Value of Transnational Medical Research: Labour, Participation and Care', (London: Routledge, 2012), 111.
[222] Ibid.
[223] Ibid.
[224] Hornblum, A.M., 'Acres of Skin: Human Experiments at Holmesburg Prison', (New York: Routledge, 1998); Kutcher, G., 'Contested Medicine: Cancer Research and the Military', (Chicago: University of Chicago Press, 2009).
[225] UNAIDS, 'Mother-to-child transmission of HIV', (October 1998),15. Retrieved from: http://www.unaids.org/sites/default/files/media_asset/jc531-mtct-tu_en_0.pdf <accessed on 21/03/2015>.
[226] Ibid.
[227] Recommendations from the meeting on mother-to-infant transmission of HIV by use of antriretrovirals, Geneva, World Health Organisation, June 23-25, 1994.
[228] Macklin, R., 'Appropriate Ethical Standards' in Emanuel, E.J., Grady, C.C., Crouch, R.A., Lie, R.K, Miller, F.G. & Wendler, D.D., (eds), 'The Oxford Textbook of Clinical Research Ethics', (New York: Oxford University Press, 2011), 299.

exploitation in research"[229]. Marcia Angell: "Acceptance of this ethical relativism could result in widespread exploitation of vulnerable Third World populations."[230] Annas and Grodin:

> Unless the interventions being tested will actually be made available to the impoverished populations that are being used as research subjects, developed countries are simply exploiting them in order to quickly use the knowledge gained from the clinical trials for the developed countries' own benefit…The central issue in doing research with impoverished populations is exploitation.[231]

The choice of placebo controls was said to be unethical[232] because, "since one significant norm of developed world research ethics requires that in most cases placebo controls not be used once some form of effective therapy exists for the illness or condition being studies" [233] as well as it "lower[ed] ethical standards, which in turn reflected a lack of equal concern for the welfare of [the] subjects [in periphery countries such as Burkina Faso and Uganda]" [234] while it was unethical for instance in the U.S. Some critics state that most of the placebo trials in the periphery countries "are not meant for the development of new drugs, but are intended merely to protect the market share of the company by adding minor variations to an already existing drug with which they hope to preserve their revenue stream once the patent of the old drug has expired."[235]

6.2.2 Trovan Trials

In 1996, a meningitis outbreak swarmed the nine states in the northern part of Nigeria, especially in Kano and Bauchi states,[236] leaving 3,000 deaths and several thousand infected.[237] Pfizer, a U.S.-based multinational corporation, conducted clinical trials of the antibiotic Trovafloxacin Mesylate, sold as Trovan, on children in Kano.[238] The research on animals at the time of the outbreak, indicated a series of severe complications associated with the Trovan use and required Pfizer to terminate the

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[229] Lurie, P. & Wolfe, M.S., 'Unethical Trials of Interventions to Reduce Perinatal Transmission of the Human Immunodeficiency Virus in Developing Countries', (1997) New England Journal of Medicine, 1854.
[230] Emanuel, E.J., Grady, C.C., Crouch, R.A., Lie, R.K, Miller, F.G. & Wendler, D.D., (eds), 'The Oxford Textbook of Clinical Research Ethics', (New York: Oxford University Press, 2011), 712.
[231] Annas, G.J. & Grodin, M.A., 'Human Rights and Maternal-Fetal HIV Transmission Prevention Trials in Africa', (1998) American Journal of Public Health, 561.
[232] This is not a binding rule even though recognised.
[233] Hawkins, J.S. & Emanuel, E.J., 'Exploitation and Developing Countries: The Ethics of Clinical Research', (Princeton and Oxford: Princeton University Press, 2008), 17.
[234] Ibid 4.
[235] WEMOS, 'The Clinical Trials Industry in South Africa: Ethics, Rules and Realities', (July 2013), 1. Retrieved from http://www.wemos.nl/files/Documenten%20Informatief/Bestanden%20voor%20'Medicijnen'/Clinical_Trials_Industry_South_Africa_2013_v3.pdf <accessed on 21/02/2015>.
[236] World Health Organization, Global Alert and Response (GAR), Cerebrospinal Meningitis in Nigeria, Disease Outbreaks Reported (19 February 1996). Retrieved from: http://www.who.int/csr/don/1996_02_19c/en/ <accessed on 13/06/2015>.
[237] Carr, D.M., 'Pfizer's Epidemic: A Need for International Regulation of Human Experimentation in Developing Countries', (2003) Case Western Reserve Journal of International Law, 28.
[238] Ibid, 29.

clinical trials home, to avail of the opportunity, it offshored the trials to Nigeria. [239] Trovan was administered to one hundred sick children while pending approval of the FDA and another one hundred sick children were given a standard meningitis treatment - cephalosporin antibiotic (ceftriaxone) –at a reduced dose, and permanently left Kano after the end of the two-week long trial.[240] Subsequently, eleven children died; five Trovan administered children and six ceftriaxone administrated children, while numerous children were severely injured; blinded, deaf, paralysed or brain-damaged.[241] Audaciously, ensuing the conclusion of the trials in Kano, Pfizer sought approval from the FDA for the paediatric use of Trovan in the U.S., only to later withdraw its application

6.3 Payment: Negating Consent and Voluntariness

Undue inducement, both in the form of monetary payment and treatment, is regarded to constitute an eminent threat in the voluntary informed consent in these countries. Such circumstances surrounding a participant is seemed to undermine the consent in terms of stripping it out of its voluntary requirement and rendering it invalid. Annas argues: "You can tell a person [in the peripheral] that this is research, but they hear they have a chance to get care or else refuse their only good chance at care. How can you put them in that position and then say they are giving informed consent?"[242] Likewise, how can an HIV-infected participant say no to a clinical trial: "If we provide antiretrovirals, will it create . . . an unreasonable inducement to participate in clinical trials?"[243]

There are several studies conducted researching effects of payment on the research participants.[244] For instance, a 2013 study published in the BMC Public Health, reported that the most participants in Brazil were motivated by "financial gain and therapeutic alternative" and not altruism, "and [even] when altruism was present, it was observed as a secondary motivator" to sign up for clinical trials.[245] In a survey conducted, 61% of IRB researchers felt "somewhat, moderately, or very concerned" that any amount of payment may influence the

[239]Amy F. Wollensack, Closing the Constant Garden: The Regulation and Responsibility of U.S. Pharmaceutical Companies Doing Research on Human Subjects in Developing Nations, 6 Wash. U. Global Stud. L.R.747, 748 (2007 756). See, also, Abdullahi v Pfizer,Inc., 2002 WL 31082956, 1 (S.D.N.Y. 2002). (Abdullahi I).
[240] Abdullahi I, 2.
[241] Ibid.
[242] LaFraniere, S., Flaherty, M.P. & Stephens, J., 'The Dilemma: Submit or Suffer', The Washington Post (Washington DC, USA) (19 December 2000): A1. Retrieved from http://www.washingtonpost.com/wp-dyn/content/article/2008/10/01/AR2008100101150.html <accessed on 19/03/2015>.
[243] Berkley, S., 'Thorny Issues in the Ethics of AIDS Vaccine Trials', (2003) Lancet 362: 992.
[244] See, for example, Deren, S., Stephens, R., Davis, W.R., Feuchet, T.E. & Tortu, S., 'The Impact of Providing Incentives for Attendance at AIDS Prevention Session', Public Health Rep. (1995) 109(4):548-54; Doody, M.M., Sigurdson, A.S., Kampa, D., Chimes, K., Alexander, B.H., Ron, E., Torone, R.E. & Linet, M.S., Randomized Trial of Financial Incentives and Delivery Methods for Improving Response to a Mailed Questionnaire', (2003) Am J Epidemiol. 157(7):643-51; Fry, C. & Dwyer, R., 'For Love or Money? An Exploratory Study of Why Injecting Drug Users Participate in Research', Addiction (2001) 96(9):1319-1325; Gilbart, E., & Kreiger, N., 'Improvement in Cumulative Response Rates Following Implementation of a Financial Incentive', (1998) Am J Epidemiol.;148(1):97-9; Little, R.E. & Davis, A.K., 'Effectiveness of Various Methods of Contact and Reimbursement on Response Rates of Pregnant Women to a Mail Questionnaire', (1984) Am J Epidemiol. 120(1):161-3 and; Ripley, E.B.D., Macrina, F.L. & Markowitz, M., 'Paying Clinical Research Participants: One Institution's Research Ethics Committees' Perspective', JERHRE (2006) 37-44.
[245] Nappo, S.A., Iafrate, G.B. & Sanchez, Z.M., 'Motives for Participating in a Clinical Research Trial: A Pilot Study in Brazil', (2013) BMC Public Health.

participant's decisions or behaviours regarding their participation.[246] 87% of the respondents were concerned that "substantial" payments will influence the participants. 67% were concerned about the impact of medical care offered to participants. Most importantly for our purposes, 85% were concerned that substantial payments "could compromise a participant's ability to think clearly about study risks and benefits, 88% reported that substantial payments "lead individuals to enroll in a trial that otherwise they would not enroll in, 84% expressed that substantial payments lead participants to remain in the study from which they would like to withdraw. 84% also stated that "completion bonuses compromise a participant's right to withdraw". Finally, the respondent's opinions on coercion and undue influence were "excessively expansive or inconsistent". Albeit, it is a fact beyond doubt that "much valuable research is unlikely to be completed in a timely way or even conducted unless research subjects are offered payment as a financial incentive to participate", the authors observed that most of the respondents were of the view that payment generates coercion or undue inducement. Notably, as the respondent's view differ, in other words are "excessively expansive or inconsistent", there should be a comprehensive "policy guidance and educational efforts… to clarify coercion and undue inducement and to address "research exceptionalism" in order to advance the goals of research ethics to promote socially valuable research while providing appropriate protection for participants". Finally, a recent study in 2014, reported that the main motivation of participants to enroll in clinical trials were: "(1) better quality treatment (availability of drugs and other medical resources) during study; (2) monetary and material incentives given to participants during study; and (3) thorough medical diagnosis of participants' health status."[247]

6.4 Peripheral Governments as Comparador

The blame does not solely rest on the Western and U.S. based pharmaceutical companies, inaffluent governments and researchers from the peripheral are zealously anticipating influx of global clinical trials into their countries, [248] due to being desperate to receive money, medical supplies and establish networks "in exchange for quickly producing citizen research subjects." [249]

Prasad accounts that iGate Clinical Research, a CRO, is marketing India as a first-rate clinical trials site. Accordingly, India may offer the following:[250]

- 40 million asthmatic patients.
- 34 million diabetic patients.
- 8-10 million people HIV positive.
- 8 million epileptic patients.

[246] Largent, E.A., Grady, C., Miller, F.G. & Wertheimer, A., 'Money, Coercion, and Undue Influence: Attitudes about Payments to Research Participants', 34 IRB: Ethics & Human Research 1 (2012): 1-8.
[247] Mfutso-Bengo, J., Manda-Taylor, L. & Masiye, F., 'Motivational factors for participation in biomedical Research: evidence from a qualitative study of biomedical research participation in Blantyre district, Malawi', (2015) J Empir Res Hum Res Ethics. , 61.
[248] Rajan, K.S., 'The Experimental Machinery of Global Clinical Trials: Case Studies from India', in Ong, A. & Chen, N.N. (eds.), 'Asian Biotech: Ethics and Communities of Fate', 58.
[249] Wang, S.S., 'Most Clinical Trials Done Abroad', Wall Street Journal, (18 February 2009). Retrieved from: http://www.wsj.com/article/SB123499424805316443.html <accessed on 05/03/2015> ; see also Glickman, S. W. et al., 'Ethical and Scientific Implications of the Globalization' (2009) The New England Journal of Medicine, 816.
[250] Prasad, A., 'Capitalising Disease: Biopolitics of Drug Trials in India' (2009), Theory, Culture & Society, 5.

- 3 million cancer patients.
- >2 million cardiac related deaths.
- 1.5 million patients with Alzheimer's disease.

Accordingly, Styhre reading Prasad write that: "it is deeply ironic that the subaltern poor population, for decades or even centuries regarded as a burden on and hindrance to the modernising Indian society and state, is now put forth as a national asset to be exploited in collaboration with foreign pharmaceutical companies."[251] The sick, now, "[c]onstitute a human capital with starkly different characteristics from, say, the software engineer who has become the iconic Indian human resource."[252] Prasad makes a grand finale: "Drug testing in India seems to be an ideal-typical case of continued capitalist exploitation of people of poorer countries by multinational companies based in the US or some European nations."[253]

6.5 Exploitation Theories

It is no surprise that the notion of exploitation, which has long been at the forefront of academia in reference to various legal issues, i.e. human/sex trafficking and child labour, is of particular prominence within the current vocabulary of bioethics. Although its implication in bioethics is not as engrained as the four commonly accepted principles, namely justice, non-maleficence, beneficence and autonomy, the concept has been finding more place in the literature of bioethics as a fundamental supplementation to the bioethical outlook that strives to prevent harm to the individuals in the first place.[254] Despite the term remains inherently connected to experiences by the periphery countries, it has today come to signify concern that extends beyond the 'developing countries'. In fact, it has been increasingly more in hand to hand use with the term 'vulnerable individuals'[255] for, after all, the starting point of the inquiry of bioethics is to assure that individuals participating in clinical trials are protected from exploitation:[256]

> The overarching objective of clinical research is to develop generalizable knowledge to improve and/or increase understanding of human biology; subjects who participate are the means to securing such knowledge. By placing people at risk of harm for the good of others, clinical research has the potential for exploitation of human subjects. Ethical requirements for clinical research aim to minimise the possibility of exploitation by ensuring that research subjects are not merely used, but are treated with respect while they contribute to the social good.[257]

Exploitation can be simply defined as the action of benefiting from an individual or resource in an unfair manner. Many scholars, however, choose to flesh out their own comprehension of the term and the fact these conceptualizations, albeit all built upon this preliminary

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[251] Styhre, A., 'Organisations and the Bioeconomy: The Management and Commodification of the Life Sciences' (UK: Routledge, 2012), 86.
[252] Prasad, A., 'Capitalising Disease: Biopolitics of Drug Trials in India' (2009) Theory, Culture & Society, 6.
[253] Ibid.
[254] Emanuel, E.J., Wendler, D., Grady, C., 'What Makes Clinical Research Ethical?' (2000) Journal of the American Medical Association.
[255] Hawkins, J.S. & Emanuel, E.J., 'Exploitation and Developing Countries: The Ethics of Clinical Research', (Princeton and Oxford: Princeton University Press, 2008).
[256] Karim, S.S.A., 'Placebo Controls in HIV Perinatal Transmission Trials: A South African's Viewpoint', (1998) American Journal of Public Health, 565.
[257] Emanuel, E.J., Wendler, D., Grady, C., 'What Makes Clinical Research Ethical?' 283 Journal of the American Medical Association 2701-11 (2000).

understanding, vary largely in their indications demonstrate the uncertainty as to the definition. The myriad of these accounts, among which are several notable normative abstractions besides those employing an array of moral arguments, can be sampled as follows:
[258]

• "[T]o exploit a person involves the harmful, merely instrumental utilisation of him or his capacities, for one's own advantage or for the sake of one's own ends."[259]

• "Exploitation necessarily involves benefits or gains of some kind to someone … Exploitation resembles a zero-sum game, viz. what the exploiter gains, the exploitee loses; or, minimally, for the exploiter to gain, the exploitee must lose."[260]

• "Exploitation of persons consists in … wrongful behaviour [that violates] the moral norm of protecting the vulnerable." [261]

• "Common to all exploitation of one person (*B*) by another (*A*)…is that *A* makes a profit or gain by turning some characteristic of *B* to his own advantage…exploitation … can occur in morally unsavoury forms without harming the exploitee's interests and … despite the exploitee's fully voluntary consent to the exploitative behaviour…"[262]

• "Persons are exploited if (1) others secure a benefit by (2) using them as a tool or resource so as (3) to cause them serious harm."[263]

• "[E]xploitation is a psychological, rather than a social or an economic, concept. For an offer to be exploitative, it must serve to create or to take advantage of some recognized psychological vulnerability which, in turn, disturbs the offeree's ability to reason effectively."[264]

Some theorists propose the non-exploitation framework to substitute the principle of equipoise.[265] The framework assesses clinical trials, during which the research participants are assigned to different treatment/trial arms, to be ethical only and insofar as the trial intervention benefits the participant and, thus, bases itself chiefly on the beneficence tenant of medical ethics. Those who adhere to the non-exploitation framework make a distinction between medical care and clinical research and concomitantly reject the beneficence principle of clinical research, arguing that such requirement may potentially hinder the progression of science. [266] The non-exploitation doctrine instead calls for the protection of the trial participants from clinical exploitation.[267] Inspired by this doctrine, Miller and Brody defend that there is no exploitation if (1) the patients are not "being exposed to excessive risks"[268]

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[258] The list is taken from Wertheimer, A., 'Exploitation', (Oxford and Princeton: Princeton University Press, 1996), 10-11.
[259] Buchanan, A., 'Ethics, Efficiency and the Market', (Totowa: Rowman and Alanheld, 1985), 350.
[260] Tormey, J.F., 'Exploitation, Oppression and Self-Sacrifice' (1974) Philosophical Forum.
[261] Goodin, R.E., 'Reasons for Welfare', (Oxford and Princeton: Princeton University Press, 1988), 147.
[262] Feinberg, 'Harmless Wrongdoing' (Oxford: Oxford University Press 1998), 176-79.
[263] Munzer, S.R., 'A Theory of Property', (Cambridge: Cambridge University Press, 1990), 171.
[264] Hill, J.L., 'Exploitation', (1994) Cornell Law Review, 637.
[265] Fredman, B., 'Equipoise and the Ethics of Clinical Research', (1987) New England Journal of Medicine 141-145.
[266] Schlichting, D.E., 'Destabilizing the 'Equipoise' Framework in Clinical Trials: Prioritizing Non-Exploitation as an Ethical Framework in Clinical Research', (2010) Nurs Philos. Oct;11(4):271-9, 274.
[267] Ibid.
[268] Excessive risks could mean: "risks that are not compensated by medical benefits to participants should not exceed a tolerable threshold, which may vary somewhat depending on the value of the anticipated scientific

for the sake of scientific investigation [non-maleficence]; and (2) the patients volunteer to "participate in an experiment rather than receiving personalised medical care directed at their best interests [informed consent]."[269]

Another notable theory of exploitation, developed by Alan Wertheimer,[270] argues that besides the harmful form of exploitation, there exist mutually advantageous, consensual, ("the exploited party has given voluntary and appropriately informed consent to the transaction.")[271] and non-consensual ("the exploited party does not give voluntary (or valid) consent.")[272] forms of exploitation. How fairness is distributed and how benefit is attained, according to Wertheimer, are crucial to determine whether or not exploitation manifests as oppression: "A oppresses B when A deprives B of freedoms or opportunities to which B is entitled. If A gains from the oppressive relationship, as when A enslaves B, then A may both oppress and exploit B. But there is no reason to think that A always gains from oppression, and when A does not gain, there is no reason to regard the oppression as exploitative."[273]

Even when a transaction is mutually beneficial and not harmful to the parties it can be exploitative. It is prima facie assumed that there is no wrong done since everyone benefits, in other words, where consent is present and benefits accrue to all parties mutually. On the other hand, others argue that exploitation is acceptable when it is not harmful and is instead mutually beneficial. In Mayer's words, each exploitative relationship begins with an "initial inequality" which renders possible the act of taking advantage. To him, therefore, there exist two types of exploitation: (1) discretionary –or flexible–; and (2) structural.[274] As exploitation comes to effect, in his eyes, when there occurs a certain degree of unfair interaction, seemingly mutually beneficial transactions have the potential to be exploitative and immoral.

Finally, the consensus among the critical scholars is that exploitation is a moral adiaphoron:

• "A society is exploitative when its social structure is organized so that unpaid labour is systematically forced out of one class and put at the disposal of another … On the force-inclusive definition of exploitation, any exploitative society is a form of slavery."[275]

• "Exploitation [in exchange] demands…that there is no reasonably eligible alternative [for the exploitee] and that the consideration or advantage received is incommensurate with the price paid. One is not exploited if one is offered what one desperately needs at a fair and reasonable price."[276]

knowledge." Miller F.G. & Brody H., 'What makes placebo-controlled trials unethical?', American Journal of Bioethics 2002;2(2), 5.

[269] Miller F.G. & Brody H., 'What makes placebo-controlled trials unethical?', (2002) American Journal of Bioethics, 5.

[270] Wertheimer, A., 'Exploitation'.

[271] Stanford Encyclopaedia of Philosophy, 'Exploitation', Retrieved from: http://plato.stanford.edu/entries/exploitation/#2 <accessed on 24/04/2015>.

[272] Ibid.

[273] Wertheimer, A., 'Exploitation', 18.

[274] Mayer, R., 'What's wrong with Exploitation?' (2007) Journal of Applied Philosophy, 137-50.

[275] Reiman, J., 'Exploitation, Force and the Moral Assessment of Capitalism: Thoughts on Roemer and Cohen', (1987) Philosophy & Public Affairs, 3-4.

[276] Benn, S., 'A Theory of Freedom', (Cambridge: Cambridge University Press, 1988), 138.

• "It is the fact that the [capitalist's] income is derived through forced, unpaid, surplus [wage] labour, the product of which the workers do not control, which makes [wage labour] exploitive."[277]

• "[A] group is exploited if it has some conditionally feasible alternative under which its members would be better off."[278]

• "[E]xploitation is seen as the failure to pay labour its marginal product…"[279]

• "An exploitative exchange is… an exchange in which the exploited party gets less than the exploiting party, who does better at the exploited party's expense… [T]he exchange must result from social relations of unequal power … exploitation can be entered into voluntarily; and can even, in some sense, be advantageous to the exploited party."[280]

• "[Capitalist] social relations … are exploitative, not only in the specific sense of extracting surplus labour, but in the more general sense of using someone as a means, utilizing her to detriment as a way of promoting one's own good…"[281]

• "Workers are exploited if they work longer hours than the number of labor hours employed in the goods they consume."[282]

• "[E]xploitation forms part of an exchange of goods and services when 1) the goods and services exchanged are quite obviously not of equivalent value, and 2) one party to the exchange uses a substantial degree of coercion."[283]

6.6 Exploitation of Clinical Trial Participants

It is a general assumption within the critical social theory that the individual is subject to an ever going structural exploitation and it can be, therefore, rightfully argued that a participant in the clinical trial setting is, regardless, subject to the exploitation as an individual living under the current social formation. The discussion of the former is not within the remit of this thesis; however, it is of extreme importance to note that until a redistribution of power comes to effect to abolishes systemic authoritarianism, in other words, until the requirements of agency is attained, voluntariness will not go beyond its pharmaceutically assumed meaning. A participant is not voluntarily participating in a clinical trial when s/he even lacks basic needs such as food, security and access to health care in the first place. To add insult to injury, law fails to protect vulnerable patients whose free agency has been lost to their illnesses.

There can always be a moral import from the definition of exploitation, however this author is interested in the descriptive conception. Such an endeavor, without doubt, necessitates an analytic investigation of the socio-economic realm.

Under which a participant's assent is of equal, if no more, importance and the possibility of a restrained choice has to be considered at all times. When one is in vital need of food, health or medical care, the so-called choice is one that is made between life and death. Under such

[277] Holmstrom, N., 'Exploitation', (1977) Canadian Journal of Philosophy, 357.
[278] Roemer, J.E., 'An Historical Materialist Alternative to Welfarism', in Elser, J. & Hylland A., (eds), 'Foundations of Social Choice Theory', (New York: Cambridge University Press, 1986), 136.
[279] Brewer, J., 'Exploitation in the New Marxism of Collective Action', (1987) Sociological Review, 86.
[280] Levine, A., 'Arguing for Socialism', (London: Version, 1988), 66-67.
[281] Kymlicka, W., 'Liberalism, Community and Culture', (Oxford: Clarendon Press, 1989), 114.
[282] Elster, J., 'Karl Marx: A Reader', (Cambridge: Cambridge University Press, 1986), 121.
[283] Moore, B., 'Reflections on the Causes of Human Misery', (Boston: Beacon Press, 1973), 53.

circumstances, the social structure itself gives realistically no other option than to choose to be exploited. Since individuals make choices in "situations of material and political precarity",[284] the specific histories[285] of individuals ultimately act as mechanisms of the structural exploitation. [286] When the participant in question is physiologically and/or socio-economically disadvantaged, the voluntariness stands no longer a valid argument to deny exploitative, even oppressive nature of the clinical trials. This is, however, not to claim that the agency is lost; it is instead subsumed, transferred and surrendered. The 'voluntariness' is indeed superseded by lack of total agency. The 'voluntariness', therefore, must take account of the structural coercion which almost predestines prospective participants' decisions to enrol in biomedical research studies. It is, thus, a necessity for bioethics to rethink ethics in conjunction with the social and economic given not only to better capture the lived experiences of research participants, but also to alleviate them.[287]

Just as Holmstrom provides, as stated above: "It is the fact that the [capitalist's] income is derived through forced, unpaid, surplus [wage] labour, the product of which the workers do not control, which makes [wage labour] exploitive."[288] Unpaid because there is no equivalent, it is forced because there is no alternative even when you think you gave consent, you have no or extremely scarce source. The social conditions force the participants and from such point of view, participants can be said to be forced to participate and their engagement with the trial does not differ at all from that of a worker's for under both categories the intent is to make a living. The elements of structural coercion and forced unpaid labour, albeit in a concealed manner, attest to a novel mode of production, otherwise known as biocapitalism, with a set of exploitative relations of production on one end of which is located the dispossessed and impoverished who have to 'choose' to sell their labour power and, on the other, the corporates that own necessary means of biomedical production to employ and exploit them.

7. The Delirium of Late Capitalism:[289] Biocapitalising the Lives of the Subaltern

[284] Boscagli, M. & Vora, K., 'Working Under Precarity: Work Affect and Emotional Labour', (June 2013), 3. Retrieved from http://escholarship.org/uc/item/0m87j6n1 <accessed on 25/05/2015>.
[285] Boscagli & Vora puts forward the following example: "[P]eople in both high-resource nations like the US and northern and western Europe, and in low-resource nations like India and China, are participating in clinical trials in order to access otherwise unavailable therapies. Ill and unable to access paid work for reasons of illness or lack of available work, such patient-workers are simultaneously performing unpaid experimental work for the pharmaceuticals industry. The specific histories of material dispossession of citizens, such as middle class patients in the US who seeks access to unaffordable or not-yet-legal experimental therapies, or unemployed day-labourers in India who seek financial resources because there are no jobs, become part of the mechanism that encourages people to consent to subjecting their bodies to risk in a way that produces potential profit for others." Ibid 3-4.
[286] Ibid, 4.
[287] Fisher, J.A., 'Expanding the Frame of "Voluntariness" in Informed Consent: Structural Coercion and the Power of Social and Economic Context', (2013) Kennedy Institute of Ethics Journal, 356.
[288] Holmstrom, N., 'Exploitation', (1977) Canadian Journal of Philosophy, 357.
[289] Cooper in *Life as Surplus* employs the concept of capitalist delirium, essentially a Freudian term, to provide a critique of biocapitalism: "the delirium of late capitalism is intimately and essentially concerned with the limits of life on earth and regeneration of living creatures –beyond the limits" which is being "translated…into the day-to-day infrastructures of government and science." Cooper, M., 'Life as Surplus: Biotechnology and Capitalism in the Neoliberal Era', (Seattle and London: University of Washington Press, 2008), 20.

The 20th century was a milestone for the technological advancements that the human societies had ever attained. This century, in deep contrast, seems likely to be shaped by these scientific developments among which is biomedicine that today seamlessly links governments, corporates and academia. The academic literature, as response to the state of affairs, has already been swarmed with a large list of new terms with bio prefixes such as biotechnology, biocapital, bioeconomy and biovalue. The theoretical interest does not only confirm the fact that the humankind has entered a new era, that of bio, but is also reflective of the fact that the life or, in other words, the "bio" has become intriguingly amenable to capitalisation and commodification. Beltrame puts it firmly:

> Life itself, in both its material embodiments and immaterial dimensions, has entered the realm of private goods, and since that time, it has been an endogenous factor of production and capital accumulation in the bioeconomy.[290]

Assignment of market value to almost everything has been by no means fresh news nor a secret; however, that the human life itself and, thereby, the very lives of individuals who together constitute the demos have become target to commodification is a novel development, harbingering a far-reaching transformation within the economic relations[291]. The society has been ensnared by bioeconomy and, in the process, for the economic device is necessarily interwoven with the political machinery, has emerged a new form of domination, otherwise known as biopolitics.[292] 'Biocapital', a term that has in no time come to popular use within the academic front, has rapidly conquered the commercial sector, giving birth to a mode of production on its own, widely regarded as biocapitalism. An array of conferences such as BioCapital Europe in Amsterdam this year and large investments as in the Quensland BioCapital Fund in 2003 worth AUD 100 million indeed stand affirmative of the interest in the issue, one that is not limited to the scientific and academic spheres and is shared equally by the tycoons of business and politics.

7.1 Commercialisation of Science

The intimate relationship between biomedicine and economy is an unsurprising result of a wider phenomenon, commercialisation of science, which has particularly marked the last three decades.[293] The concordant privatization of science has today made the scientific study

[290] Beltrame, L., 'A New Socially Distributed (Bio)Economic Growth? Some Theoretical Reflections', Conference Paper, 3. Retrieved from: www.sts.aau.at/ias/content/download/7389/61636 <accessed on 15/05/2015>.

[291] Biocapitalism, despite it is in essence capitalism, differs from its predecessors and contemporaries in that it denotes a bios capacity to produce surplus value. The commodification of the life does not redefine the system of capital exchange and circulation, but also establishes a regime of intellect in which the life sciences is crowned as the foundational epistemology. Rajan, K.S., 'Subjects of Speculation: Emergent Life Sciences and Market Logics in the United States and India', (2005) American Anthropologist, 111.

[292] For a sampling of literature discussing biopolitics, see generally Macklin, R., 'The New Conservatives in Bioethics: Who Are They and What Do They Seek?',(Hastings Centre Report, Jan.-Feb. 2006), 34; Cohen, E., 'Conservative Bioethics & the Search for Wisdom' ,(Hastings Centre Report, Jan.-Feb. 2006,) 44; Kass, L.R., 'Reflections on Public Bioethics: A View from the Trenches',(2005) Kennedy Institute of Ethics Journal', 221; Powers, M., 'Bioethics as Politics: Bioethics as Politics: The Limits of Moral Expertise' ,(2005) Kennedy Institute of Ethics Journal 305.

[293] Many scholars have noted the profound changes that science is undergoing. See, for example, Gibbons, et al., Nowotny H. and Ziman J.

an integral part of the global financial order,[294] compelling the public and academic institutions to operate within the mind-set of the market economy. As would be anticipated,[295] such commercialisation of science has crafted the necessary status-quo for the capital owners to appropriate the intellect and reconfigured science into what critical theorists today refer to as "Mode 2 knowledge production" (Gibbons, et al, 1994), "academic capitalism" [296] and "post-academic science"[297]. Profit seems to be the fundamental driving force of scientific work whereas striving for public good has become a mere rhetoric and only a discursive shield. The academic capitalism, Slaughter and Rhodes explain, is a great opportunity to the profit for the triple helix of industry-university-government. [298] Rajan and Birch agree with Slaughter and Rhodes and further point out how universities, local enterprises and multinational pharmaceutical giants act together to conduct research, mainly employing post-Fordist methods and strategies.

The knowledge as a property reaps from all that scientific work has to offer and the same is no less valid when it comes to the health sector which is today a major field of the corporate activity.[299] In fact, in Beltrame's view, the process was intimately related with the neoliberal conquest of the mainstream economic theory. Biological and medical fields have in no time epitomised the triumph of the neoliberal hegemonic order. The concurrent retrenchment of the property rights, on the other hand, has further enabled a more complete exploitation of research findings.[300] The drive to profit, thereby, has given rise to what is known to political economists as bioeconomy, which is, according to Styhre, where intersect "the life sciences and the capitalist regulatory system".[301] Such endogenization of scientific knowledge within the neoliberal market implies that bioeconomy works through the privatization of biological knowledge, information, and materials. This monopoly over biomedical knowledge is an "economic regime wherein all sorts of know-how pertaining to the management of health and life per se are turned into marketable commodities and services."[302]

7.2 From Biopolitics to Biocapitalism

While, as aforementioned, clinical trials sponsored by the biocapitalist institutions are no more conducted with an iota of intent to alleviate the social life, the political device also

[294] Tyfield, D., 'The Economic of Science: A Critical Realist Overview. Volume 1: Illustrations and Philosophical Preliminaries', (London: Routledge, 2011), 6.
[295] As aforementioned, the commercialisation of science and the emergence of bioeconomy can be said to be related to events such as Cohen-Bayer Affair, Bayh-Dole Act and Chakrabarty decision.
[296] Slaughter, S. and Rhoades, G., 'Academic Capitalism and the New Economy: Markets, State, and Higher Education', (Baltimore: John Hopkins University Press, 2004).
[297] Ziman, J, M., 'Real Science. What it is, and what it means,' (Oxford: Cambridge University Press, 2000). Ziman argues that academic and industrial science amalgamated into a new societal form –post academic science –that is based on market principles producing proprietary knowledge its research being commissioned to achieve practical goals for to generate financial gain.
[298] Leydesdorff, L. & Etzkowitz, H., 'Emergence of a Triple Helix of University-Industry Government Relations', (1996) Science and Public Policy 279-286.
[299] Rose, N., 'Politics of Life Itself: Biomedicine, Power, and Subjectivity in the Twenty-First Century', (Princeton: Princeton University Press 2007), 3.
[300] Styhre, A., 'Organisations and the Bioeconomy: The Management and Commodification of the Life Sciences' (UK: Routledge, 2012), 25.
[301] Styhre, A., 'Knowledge Sharing in Professions: Roles and Identity in Expert Communities', 85.
[302] Styhre, A., 'Organisations and the Bioeconomy: The Management and Commodification of the Life Sciences' (UK: Routledge, 2012), 29.

seems to have shifted its attention from a "politics of health" to a "politics of life"[303].[304] Such exercise of institutional power on bodies has been profoundly transformative of the human life in an explicit manner that contributed invaluably to the continuity of the modern class society.[305] Foucault claims that the power is exercised on two levels, (1) anatomopolitics – which, to him, is the power exercised over individual human bodies–; and (2) biopolitics – which is, in contrast, targeting bodies of the population–.[306]

The adoption of neoliberal recipes within the biomedical field can be seen as an expansion of biopower, herein used within the Foucauldian scope, through which the life is administered[307]. It is Tomso, however, who, in a very much Marxian manner, stresses the paradox of neoliberal biopower which, within the material base, has objectified human body into a means of production while, on the ideological level, continuously promised greater individual freedom. [308] Haraway contends, likewise, that the notion of biopower encompasses both Marx and Foucault; Haraway, however, goes further to expand the meaning of the term in an attempt to transcend the "own species chauvinism" and underlines the necessity to recognize all creatures as the subjects of the decretorial biopower."[309]

Biocapital, on the other hand, is as important as the biopower is to the profit driven biomedicine since biopolitics and bioeconomics are inextricably intertwined[310]; as a matter of fact, biocapital and biopower stand in correlation and necessarily coexist for the two do not only supplement, but also reproduce one another[311]. Transnationally dominant, this "lively

[303] Styhre, A., 'Knowledge Sharing in Professions: Roles and Identity in Expert Communities', 85.
[304] At the risk of simplification, one may say that the vital politics of the eighteenth and nineteenth centuries was a politics of health –of rates or birth and death, of diseases and epidemic, of the policing of water, sewage, foodstuffs, graveyards, and of the vitality of those agglomerated in towns and cities…[t]he vital politics of our own century looks quite different. It is neither delimited by the poles of illness and death, nor focused on eliminating pathology to protect the destiny of the nation. Rather, it is concerned with our growing capacities to control, manage, engineer, reshape, and modulate the vital capacities of human beings as living creatures. It is, I suggest, a politics of life itself". Rose, N., 'Politics of Life Itself: Biomedicine, Power, and Subjectivity in the Twenty-First Century', (Princeton: Princeton University Press 2007), 3.
[305] Lysaught, M.T., 'Docile Bodies: Transnational Research Ethics as Biopolitics', (2009) Social Justice, Paper, 487.
[306] Foucault, M., 'The History of Sexuality: An Introduction', Hurley, R. (trans.), (New Yok: Pantheon Books, 1978), 139, 140; Foucault, M., 'Society Must Be Defended: Lectures at the College de France (1975-76)', Bertani, M. & Fontana, A. (eds.), Macey, D. (trans.), (London: Allen Lane, 2003). 245.
[307] Biopolitics was reconfigured by Foucault in the mid-1970s while teaching at the Collège de France and writing *The History of Sexuality*, first introducing the concept of biopower. It is important to note that Foucault's untimely death, left a wide door for interpretation of his concept of biopower and biopolitics.
[308] Boggs, C.G., 'Animalia Americana: Animal Representations and Bipolitical Subjectivity', (New York: Columbia University Press, 2013).
[309] Ibid.
[310] Styhre, A., 'Organisations and the Bioeconomy: The Management and Commodification of the Life Sciences', (UK: Routledge, 2012), 25.
Biocapital is creating a series of cultural transformations in the materiality and exhangeability of what we call 'life'. These transformations are created through shifting and variable use of market commodification versus public commons or public good transformation, both of which are disciplined by new forms of capitalist logic, conforming neither to those of industrial capitalism nor to those of so-called postmodern information capitalism. This is the rationale for the term 'biocapital' which asks the question of how life gets redefined through the contradictory processes of commodification."
[311] Kaushik S.J., 'Biocapital: The Constitution of Postgenomic Life (Durham: Duke University Press, 2006), 47; and Rose, N., 'Politics of Life Itself: Biomedicine, Power, and Subjectivity in the Twenty-First Century', (Princeton: Princeton University Press 2007), 7.

capital" is a "promissory capital"[312] an essential ingredient of the "speculative capitalism" where the investment takes place based on assumptions on what may be profitable.[313]

Along with the neoliberal conquest of the science has come into effect the marriage of the laboratory and the factory, interlinking clinical research and industry.[314] This has resulted in greater influence of the market, as Styhre highlights, over the researchers' agenda:[315]

> The market-orientation of Big Pharma is translated into a research agenda aiming for so-called lifestyle diseases (e.g., diabetes, obesity, cardiovascular disease) rather than more pressing tropical diseases such as dengue fever, malaria and tuberculosis, killing millions of f people in developing countries. Like all capitalist companies, Big Pharma tends to go where the money is.[316]

The inaction of the peripheral countries to make necessary legislations to regulate clinical trials renders their vulnerable citizens defenceless against the transnational enterprises' profit driven mistreatment of the human bodies. The lack of statutory measures, which allows the commercialisation of the citizens themselves, cannot be assessed as a simple case of unawareness; it seems, on the contrary, that the neoliberal governance wilfully chooses to remain silent and it benefits from such an indifference for it enjoys a share of the surplus value accumulated during the process. Ong concludes that such major lacuna in law is cherished by the State as a site of biopolitics:

> A focus on neoliberalism recasts our thinking about the connection between government and citizenship as a strictly juridical legal [sic] relationship. [Neoliberal states use] a biopolitical mode of governing that centers on the capacity and potential of individuals and the population as living resources that may be harnessed and managed by governing regimes …. The elements we think of as coming together to create citizenship—rights, entitlements, territoriality, a nation—are becoming disarticulated and rearticulated with forces set in motion by market forces.[317]

7.3 Biocapitalising Clinical Trial Participants

Since the science and technology took the neoliberal path, they have given up their original purpose, that they are supposed to improve the societal circumstances, and enhance the quality of human life, and have, thus, turned out exploitative means in the dystopic realm of the biocapitalism where the citizens who, from the neoliberal point of view, are reduced to bodies which are sites of both experimenting and exercising biopower. This is, nonetheless, not to deny that the citizens do not matter to the system. In fact, each individual is a valuable,

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[312] Thompson, C., 'Making Parents: The Ontological Choreography of Reproductive Technologies', (Cambridge: MIT Press, 2005), 248-249.
[313] Rajan, K.S., 'Subjects of Speculation: Emergent Life Sciences and Market Logics in the United States and India', (2005) American Anthropologist, 21.
[314] Rose, N., 'Politics of Life Itself: Biomedicine, Power, and Subjectivity in the Twenty-First Century', (Princeton: Princeton University Press 2007), 31
[315] Styhre, A., 'Knowledge Sharing in Professions: Roles and Identity in Expert Communities', 87.
[316] Ibid, 88.
[317] Ong A., 'Neoliberalism as exception: Mutations in citizenship and sovereignty' (Durham and London: Duke University Press, 2006), 6.

but only insofar as their body counts as more surplus to be collected in the vaults of the corporate.

The situation is way more severe within the peripheral where the State machinery has acquired a comprador quality under the neoliberal globalization. Barbados where a CRO has come to agreement with the government for conducting trials on racially homogenous stands demonstrative of the hideous biopolitics intrinsic to the periphery.[318]

8. Clinical Trial Participants as Labourers

To develop a concept of capital it is necessary to begin not with labour but with value.
—Karl Marx, Grundrisse

For the system to survive, in other words, in order for pharmaceutical companies to maintain and maximise their profit, it must constantly sustain its 'mode of production'. In the mechanic of mode of production, where do we position the participants? Are they productive forces or are they the capital itself? Departing from the quotation above, the economic value of clinical trials enables the recognition of participants as workers. To produce a drug or treatment, the labour of the participants is required. Their labour is formulated to be profitable for the companies as their primary aim is to bring in profit for shareholders, investors and other elite stakeholders when they commercialise the drug and/or treatment. As long as the work leads to or will potentially lead to commercial profit, it is labour.

The pharmaceutical companies are pharisees, science and health has been commercialised and yet participants are expected to be altruistic volunteers while the rich reap and multiply profit thanks to the participants' labour. The nature of their work has been deliberately concealed under the language of citizenship and public good. The participants' labour should not be kept outside of the market relations. Their bodies create a resource with commercial potential. Furthermore, unless, categorised as worker, the clinical trial participant will remain being subaltern and there will be a "structural impossibility of such a figure being a political subject," and when they do politically mobilise, "would be through pain and/or death, for instance through a likely scandal that would result from a serious adverse event in a clinical trial."
[319]

Protection of participants and legal accountability of pharmaceutical companies or CRO can be attained via contractual obligations as seen from the earlier case-law that where law stands now is unsatisfactory and leave the participants without adequate remedies and protection. Furthermore, classifying the participants as workers will alleviate many sufferings.

Bioethical guidelines speak of undue inducement and coercion when payment is provided as it undermines the informed consent, however it is the guidelines' that define participants' participation as voluntary.

[318] The authors also caution: "These examples reveal future directions of the stratification of biomedicalisation by race, class and citizenship." Clarke, A.E., Shim, J.K., Mamo, L., Fosket, J.R. & Fishman, J.R., 'Biomedicalization: A Theoretical and Substantive Introduction', in 'Biomedicalization: Technoscience, Health and Illness in the U.S.', (Durham: Duke University Press, 2010), 9.
[319] Rajan, K.S., 'The Experimental Machinery of Global Clinical Trials: Case Studies from India', in Sismondo, S. & Greene, J.A. (eds), 'The Pharmaceutical Studies Reader', (Chichester: John Wiley & Sons, 2015), 231.

8.1 The Guild of 'Tube-Swallowers'

An anecdote will set the context of this thesis' argument. Dr. William Osler Abbott in early 1930s was developing his new gastroenterological technique for treating obstructions in the human small intestine. First testing on himself, found it to be a "waste of time" and instead focused on the "capture, selection, care and training of good healthy human guinea pigs".[320] Despite the Great Depression, he could not find any healthy individuals willing to accept his $2 job as a human subject: "In that day of poverty, destitution and collapsing homes, not one solitary subject did I ever get through the very agencies that were apparently striving to find jobs, to make jobs, to beg jobs of any kind for hungry men." Abbott also could not recruit, "beggars," "tramps, vagrants, and the unemployed." He finally succeeded when a "black janitor on the hospital floor" brokered for him. Never had he expected a strike, yet in 1935, Abbott learned that human research subjects "are apt to be human": "Double the pay or no demonstration was the demand. That was a bad few minutes for me. No dogs, cats, rats or rabbits that I had ever handled had done this, but there was one opening left." At the 11th hour of the strike, he found new volunteers of medical students: "a shipment of scab labour . . . that would have made any factory foreman green with envy." At the time, "the National Labour Relations Board" was not yet established and Abbott "had the pleasure of indulging in a little old-fashioned capitalism. We fired the whole lot of them, lock, stock and barrel. The exhibit went off like clockwork." Subsequently, he started to advertise in newspapers and "the honourable and rapidly growing guild of tube swallowers [was] well established."

Decades after Abbott, the features of clinical trials have not changed immensely; advertisements, payment for participation and recruitment based on health (just like Phase I clinical trials) and willingness to cooperate. It is clear that Abbott perceived his subjects as workers. However, the successors of Abbott classify the participants into weak categories based on participant's identity and circumstances.

8.2 Why Worker?

Clinical trial participants' labour have been called 'clinical labour' by Waldby and Cooper,[321] whereas Clarke, Shim, Shostak and Nelson utilises 'biolabour'.[322] Clinical trial participants themselves have been called; volunteers, human/research subjects, professional guinea pigs,[323] guinea pigs, professional volunteers,[324] but rarely as workers.[325]

Clinical trial participants are engaged in a labour that is not conventionally conceptualised as work thus remain hidden from the public realm. The clinical trial work is disregarded within the boundaries of "market work and leisure, economic coercion and choice, embodied and

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[320] Abbott, W.O., 'The Problem of the Professional Guinea Pig', Proceedings of the Charaka Club 10 (1941): 249-60, 249.
[321] Waldby, C. and Cooper, M., 'The Biopolitics of Reproduction: Postfordist Biotechnology and Women's Clinical Labour', Australian Feminist Studies (2008) 23(55), 59.
[322] Clarke, A., Shim, J., Shostak, S. and Nelson, A., 'Biomedicalising Genetic Health, Diseases and Identities', in Atkinson, P., Glasner, P. and Lock, M., (eds.), 'Handbook of Genetics and Society. Mapping the New Genomic Era', (London: Routledge, 2009), 22.
[323] Abadie, R., 'The Professional Guinea Pig: Big Pharma and the Risky World of Human Subjects', (Durham: Duke University Press, 2010) and Abbott, W.O., 'The Problem of the Professional Guinea Pig', Proceedings of the Charaka Club 10 (1941): 249-60, 249.
[324] Agredo, S., 'Professional Volunteers: Human Guinea Pigs in Today's Clinical Research'. Retrieved from https://globalbioethicsdotnet.files.wordpress.com/2014/03/agredo-professional-guinea-pigs.pdf <accessed on 21/06/2015>.
[325] Throughout my research I have encountered very limited amount of literature that categorised clinical trial participants as workers.

disembodied labour, commercial and social labour and virtual and material work." Their work seems to fit under the modern economic, legal and social trends that include "outsourcing and marketisation of services; degradation and fragmentation of employment structures; waning state protections of work; rising consumption…and appearance industries; expanding platforms of technology…; and growth of globalization, offshoring, and multinational firms."[326] Mostly, the participant's contribution is framed under the gift/voluntary economy, where the individual offer his/her body for advancement of science, in other words, purely out of altruism. However, clinical trial participant labour is market-driven, often informal, nonetheless is definitely a form of labour. Thus, their labour has a foundational economic part in marketing drugs, thus a direct form a market recognition for their role must be recognised and granted.

Ackerman argues for the characterisation of research participants as workers (paid-employees) and for the just treatment of them as labourers.[327] He contends that the exceedingly risky nature of participation should not be differentiated from the work of fire fighters that is dangerous but socially beneficial and indispensable. Thus if fire fighters and soldiers are getting paid, so should the participants. Moreover, when even persons engaged in solely dangerous work such as race car drivers or trapeze artists are permitted to receive substantial amount of payment so should the clinical trial participants who ameliorate the welfare of the society. Payment he avers, protects the moral interests of the participants. Folayan and Allman, taking a labour market perspective, argue that clinical trial participants can be classified as workers. [328] Rightfully, while arguing that the participants' new status "opens space to consider ways to link global health to the economic empowerment of individuals", they caution that "the payment of wages has the potential to entrench inequities."[329]

Cooper and Waldby, in *Clinical Labour: Tissue Donors and Research Subjects in the Global Bioeconomy*,[330] scrutinise the market for labour in clinical research through the lens of Marxism. The two provide that "the nature of the capitalist labour...crucially depends on the exposure of certain bodies to uninsured risk". Grounding on this quotation, resonating that of Ackerman's, it can be argued that clinical trial participants are workers. The participants enrolled in Phase II and Phase III studies "work for healthcare", while their driving force is to access health-care. For the authors, this situation creates "coercion associated with 'workforce' regimes, where welfare recipients are required to work in exchange for social benefits or health care." The underprivileged chronically-ill patients participate in later-phase trials in order to access drugs.

[326] Washington University Law, 'Invisible Labor Colloquium' (2013) Retrieved from http://www.law.wustl.edu/centeris/pages.aspx?ID=9567 <accessed on 07/03/2015>.
[327] Ackerman, T., 'An Ethical Framework for the Practice of Paying Research Subjects', (1989) Ethics and Human Research, 1.
[328] Folayan, M.O. & Allman, D., 'Clinical Trials as an Industry and an Employer of Labour', in Kelly, A.H. & Geissler, P.W. (eds.) 'The Value of Transnational Medical Research: Labour, Participation and Care', (London: Routledge, 2012), 13.
[329] Ibid.
[330] A reviewer described the analysis as having the potential of giving "heartburn" to the industry. Cooper, M. & Waldby, C., 'Clinical Labour: Tissue Donors and Research Subjects in the Global Bioeconomy', (Durham: Duke University Press, 2014).

Some hold the opinion that participants have to be paid, however, as unskilled employees. [331] Such commentary perceives the participant activity to be labour, but one of the kind that needs no beforehand training.[332] According to this recommendation a clinical trial participant in South Africa will receive the same hourly rate with, for instance, an unskilled employee in the branch of civil engineering which corresponds to almost R10.00 per hour.[333] The participant, even if is accordingly paid, is not in reality compensated for the monetary gain his actual work makes for the corporate; yet, for the purposes of equitability, they have to be paid for the actual time's worth since.[334]

8.3 Finding a Common Ground

The U.S. recognises that the participants should be reimbursed in some way as long as it does not lead to coercion and undue inducement.[335] Thus, there is a recognition that the participants' valuable contribution has a monetary value. Payment is contingent on factors such as:

a. "Is the study recruiting healthy individuals who do not have the condition under investigation, or individuals who may receive medical benefit from participation?
b. What are the potential risks of participation?
c. How much inconvenience is expected due to the number and length of study visits?"[336]

FDA regards payments as recruitment incentives and not as benefits,[337] and in an empirical study conducted by Largent et al, it was found that IRB researchers was of the view that payments should be given for incurred expense for participation and not as incentive or

[331] NHREC, 'Payment of Trial Participants in South Africa: Ethical Considerations for Research Ethics Committees (RECs)' (2012), 3. Retrieved from https://www.ru.ac.za/media/rhodesuniversity/content/ethics/National%20Guidelines%20for%20Payment%20of%20Participants%20in%20Clinical%20Trials%20(2012).pdf <accessed on 11/06/2015>.
[332] Ibid.
[333] Ibid.
[334] Ibid.
[335] Since payment of participants present ethical issues regarding the requirement of voluntary participation, IRB appears to ensure that payment will not present coercion and undue inducement, one of the ways the U.S. tries to avoid exploitation is to eliminate the potential coercion and undue inducement in clinical trial participation with relation to payment. Under the Belmont Report coercion "occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance," whereas undue influence occurs through an offer of excessive, unwanted, inappropriate or improper reward or other overture in order to obtain compliance." The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 'The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research', (Washington, DC: Government Printing Office; 1979).
The Common Rule further provides the only considerable guidance available: "An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimise the possibility of coercion or undue influence". 45 Code of Federal Regulations 46.116
[336] Roth, M.T. 'Paying Participants to Take Part in Addiction Research: Ethical Considerations'. Retrieved from: http://www.bu.edu/aodhealth/issues/issue_nov12/feature112012.html <accessed on 09/05/2015>.
[337] Office of Human Research Protection. IRB Guidebook (2001).
Furthermore, "Such problems might occur, for example, if the entire payment were to be contingent upon completion of the study or if the payment were unusually large. Payments should reflect the degree of risk, inconvenience, or discomfort associated with participation." Ibid.

compensation for risk.[338] The researches preferred participants participating out of altruism.[339]

This "financial incentive" is utilised when "health benefits to [participants] are remote or non-existent".[340] There is a discrepancy between payment practices.[341] Likewise, there is a discord regarding the delineation of payment to participants; should it be referred to as 'compensation', 'incentive' or 'benefit'?[342] For instance, in advertisements for recruitment, words 'payment' or 'reimbursement' is favoured over 'compensation'.[343]Grant and Sugarman on the appropriateness of using incentives assert that:

> Incentives can be used to recruit subjects in many situations without any ethical qualms where all other ethical criteria are met — that is to say, incentives themselves are not the ethical problem here, generally speaking.… We have argued that incentives become problematic when conjoined with the following factors, singly or in combination with one another. Where the subject is in a dependency relationship with the researcher, where the risks are particularly high, where the research is degrading, where the participant will only consent if the incentive is relatively large because the participant's aversion to the study is strong, and where the aversion is a principled one — when these conditions are present, the use of incentives is highly questionable.[344]

Under the various proposed models of making payment to subjects for trial participation, some more ethically acceptable than the others. The common models are: [345]

1. The market model
2. The wage model
3. The reimbursement model
4. The appreciation model

There are some who naively believe that:

> One needs to understand that clinical research is the process for transforming the biomedical research done by today's generation for the improved medical practice of the generation of tomorrow. Spreading awareness that the basic objectives of clinical research are improvement of disease outcome and improvement of quality and

[338] Largent et al, 1.
[339] Ibid.
[340] Food and Drug Administration, 'Basic Questions and Answers about Clinical Trials'. Retrieved from http://www.fda.gov/ForConsumers/ucm121345.htm <accessed on 25/05/2015>.
[341] Ackerman, T., 'An Ethical Framework for the Practice of Paying Research Subjects', 11 IRB: Ethics and Human Research 4 (1989): 1-4, 1.
[342] Meyer, M., 'Regulating the Production of Knowledge: Research Risk-Benefit Analysis and the Heterogeneity Problem', (2013) Administrative Law Review 2, 237-298.
[343] Guideline for Recruitment Materials and Payment of Research Subjects. Retrieved from http://rochester.edu/ohsp/documents/ohsp/pdf/policiesAndGuidance/703a_GDL_Recruitment_and_Payment.pdf <accessed on 01/06/2015>.
[344] Grant, R.W. & Sugarman, J., 'Ethics in Human Subjects Research: Do Incentives Matter?' (2010) Journal of Medicine and Philosophy: A Forum for Bioethics and Philosophy of Medicine,732-733.
[345] Grady, C., 'Payment of clinical research subjects' (2005) Journal of Clinical Investigation, 681-7.

> efficiency of the healthcare system could help in changing the perception of research participants as guinea pigs and could help mitigate the researcher's problems to a certain degree. The ideal situation would be when subjects volunteer for the altruistic reasons rather than for the material gains. Until then, let us learn from the debates and experience and remember the ethical concerns that guide clinical research.[346]

Expecting participants to risk their lives for purely altruistic reasons, namely, for the benefit of the future patients is disseminating the view of the big pharmaceutical elites is absurd. This is not to say that a disadvantaged participant who wants to volunteer for a clinical study should not be permitted to volunteer or should not volunteer, only that it should be only being employed as a worker will prevent exploitation.

Thus, FDA creating its own narrative, allows for some amount of payment. When the payment goes beyond to constitute to be 'coercive' or will cause 'undue inducement' it does not allow because that will contaminate the voluntariness of the participation according to them. Perhaps, it is in the best interest of all parties, to follow the clever strategy to pay the participants for their engagement in clinical activity for their valuable contribution to the trial, but restrict the amount paid for their involvement in the research to that of an unskilled worker. [347]

8.4 Categorising Participants as Labourers under Marxist Conception

The bodies of the participants are more and more accessible for private investments and capitalisation in bioeconomy and of science and yet invisible and unrecognised. The advocates of clinical trial participant's exploitation will argue that they are volunteers thus they are free to leave whenever they wish to do so. Akin to the discussion on exploitation above-mentioned, structural exploitation does not offer a choice. Thus, if a participant is participating for money or access to treatment and/or drug, there is a reciprocity situation, which should absent in a voluntary situation. Labour is forced as if a participant does not enrol in that s/he will work elsewhere and/or will remain sick and perhaps die. This author does recognise that the labour of the participants is exploited labour and it ensues injustice. Nevertheless, recognition of the participants as workers is the best possible way of their protection against the corporates at the moment.

To elaborate, the liberal school of thought asserts that an individual has autonomy and, therefore, is free to sell or offer his/her labour; however, this is an insufficient claim. On the contrary, an individual is forced to sell or offer it as the ruling class maintains a monopoly over the means of production and distribution. As Marx articulates, "[Capital] obtains this surplus-labour without an equivalent …in essence it always remains forced labour –no matter how much it may seem to result from free contractual agreement". In the words of Holmstrom, as above-mentioned, exploited labour is: "forced, surplus, and unpaid labour, the product of which is not under the producers' control"[348].[349]

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[346] Pandya, M. & Desai, C. 'Compensation in clinical research: The debate continues', Perspectives in Clinical Research (2013).

[347] Dickert, N., 'Enrollment of Economically Disadvantaged Participants in Clinical Research', Virtual Mentor, (January 2009). Retrieved from: http://journalofethics.ama-assn.org/2009/01/pfor1-0901.html <accessed on 01/06/2015>.
Retrieved from: http://journalofethics.ama-assn.org/2009/01/pfor1-0901.html <accessed on 01/06/2015>.

[348] Holmstrom, N., 'Exploitation', (1977) Canadian Journal of Philosophy, 357.

[349] Peffer, R.G., 'Marxism, Morality, and Social Justice', (Princeton: Princeton University Press, 2014), 145.

8.5 What's in a name?

The subaltern clinical trial participants have no voice and are unrecognised. Classifying them as workers can lead to them uniting under labour unions, safe conditions of work, insurance schemes, compensation, etc. Moreover, clinical trial participant as workers can enforce established international labour standards against employer-transnational corporations on the foot of ATS.[350]

Participation of a clinical trial participant is labour, it is an unusual form of labour thus unrecognised, for instead of a work being completed by the participant, the participant gives access to his/her body. Accordingly, after the classification, the participant can avail of the rights recognised under the International Labour Organisation (ILO). ILO has branded four core standards in its 1998 Declaration on Fundamental Principles and Rights at Work: the elimination of all forms of forced or compulsory labour; the elimination of discrimination in respected of employment; the effective abolition of child labour; and the freedom of association and the effective recognition of the right to collective bargaining.[351] The Declaration states that all members have to ensure and are bounded by these core standards on the face of their membership regardless if they have ratified the eight ILO conventions where these standards were derived from. [352]

Clinical trial participants could be categorised as workers with fixed-term contract as under temporary employment. This type of contracts are "for a given duration, which may be formally recorded as a definite end-date and/or as a definite task."[353]

1. Temporary employment;
2. Atypical/casual worker; and
3. Hazardous work.

Cooper and Waldby argue that, "the transformation of labour relations depends on radical political critique rather than juridical reform, and social protections do not engender but follow in the wake of such disruptions."[354] Legal implementation will follow once a discussion and awareness have started, not before that. Thus this author is of the opinion that,

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[350] See, for example, Cleveland, S., 'Global Labour Rights and the Alien Tort Claims Act', 76 Tex. L. Rev. 1533 (1998) and Torres, M., 'Labour Rights and the ATS: Can the ILO's Fundamental Rights be Supported Through ATS Litigation?', 37 Colum. J.L. & Soc. Probs. 447 (2004).

[351] ILO, ILO Declaration on Fundamental Principles and Rights at Work.

[352] The eights convention are: (1) ILO Convention No. 19 – Convention concerning Forced or Compulsory Labour (28 June 1930), 39 U.N.T.S. 55; (2) ILO Convention No. 15 –Convention concerning the Abolition of Forced Labour, (25 June 1957), 320 U.N.T.S. 291; (3) ILO Convention No. 87 – Convention concerning Freedom of Association and Protection of the Right to Organise, (9 July 1948), 68 U.N.T.S. 17; (4) ILO Convention No. 98 –Convention concerning the Application of the Principle of the Right to Organise and to Bargain Collectively, (1 July 1949), 96 U.N.T.S. 257; (5) ILO Convention No. 100 –Convention concerning Equal Remuneration for Men and Women Workers for Work of Equal Value, (19 June 1951), 165 U.N.T.S. 303; (6) ILO Convention No. 111 –Convention concerning Discrimination in Respect of Employment and Occupation, (25 June 1958), 362 U.N.T.S. 31; (7) ILO Convention No. 138 –Convention concerning Minimum for Age for Admission to Employment, (26 June 1973), 1015 U.N.T.C. 297; and (8) ILO Convention No. 182 – Convention concerning the Prohibition and Immediate Action for the Elimination of the Worst Forms of Child Labour, (17 June 1999), 38 I.L.M. 1207.

[353] Cazes, S. & de Laiglesia, J.R., 'Temporary Contracts, Labour Market Segmentation and Wage Inequality', (June 21, 2014), 2. Retrieved from: www.iza.org/conference_files/worldb2014/**cazes**_s4773.pdf <accessed on 12/02/2015>.

[354] Cooper, M. and Waldby, C., 'Clinical Labour: Tissue Donors and Research Subjects in the Global Bioeconomy' (Durham: Duke University Press, 2014).

this thesis has initiated such a discussion which will hopefully result in legal reform to improve the standards of clinical trial participants.

International community is concerned about clinical trial participants, as exemplified from the myriad codes and regulations. However, the fruit of their worry, i.e. the ethical framework for the participants'' protection, have so far failed. Thus, for a substantive vindication of the participants' rights, their recognition as workers is fundamental. The governments are involved in the pharmaceutical clinical trials. Against this backdrop it is up to the employment lawyers and the bioethical community now to establish a framework to include clinical trial participants as workers in order to afford them rights, to seek accountability in case of an adverse event and to be safeguarded.

9.Conclusion

There must be additional safeguards created to protect and uphold human life and dignity. These measures could include, monitoring bodies and an international regulation preventing corporate greed and neoliberal policies of states. However, the exploitation of the peripheral will not end. The categorization of the clinical trial participants as workers is essential.

The progress in life sciences have enabled the furtherance of human lives, at least for those in privileged classes. While the lives have turned into marketable value. The only viable way to move forward is to accept that structural exploitation governs clinical trials. Furthermore, the only avenue to debilitate their exploitation will be through their categorisation as workers. The discussion of the case-law pertaining the ATS, the weakness of the ethical and regulatory frameworks, the way clinical trial participants' bodies' are turned into marketable concomitantly capitalised, how the participants' are subjected to structural exploitation all are signals calling for change. The science that further our lives should not make us suffer.

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