CHIM consent harm and law

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**LAW AND ETHICS IN CONSENSUAL HARM DOING**

**Introduction**

The Controlled Human Infection Model (CHIM) trials are conducted on healthy human beings, who are intentionally infected with a disease (the infectious organism could be close to wild-type pathogens, adapted or attenuated from wild-type with less or no pathogenicity, or genetically modified in some manner)([[1]](#endnote-1)), in a controlled environment, so that science can find out the path of infection, what is happening at the molecular and cellular level, and find the best time for medical intervention, develop a cure and/ or prevention methods against the infection ([[2]](#endnote-2)). CHIM experiments have taken place for diseases like small pox (more than a century ago), *dengue,* malaria, influenza, tuberculosis, typhoid, etc. While the WHO guidance document states that it would be inappropriate to do CHIM trials for diseases that are virulent or even an attenuated organism for example those that have a high fatality rate or a long uncertain period of latency, it does speak of the necessity of CHIM trials in very few circumstances and the caution with which the trials should take place (i).

The justifications often given to conduct CHIM trials are that it accelerates the development of vaccines or treatments, by using lesser financial and human resources than clinical trials ([[3]](#endnote-3)). But, can less use of resources be enough of a justification to intentionally harm another human being? What about the legal and ethical obligations of the researcher “to do no harm” (non-maleficence) to research participants?

Scientist and researchers by infecting healthy people, inducted as research participants, do cause “controlled” harm to them. Can we, for the sake of advancement of science, justify exposing individual research participants to harm by infecting them with a disease? Do individuals have a right to submit themselves to harm, even though it may be in a controlled setting, and minimal? Can taking informed consent for intentional harm or for taking such a risk of harm, nullify the harm doing? This article measures some of these legal and ethical challenges raised in CHIM trials.

**The Harm Principle**

John Stuart Mill’s famous words in his philosophical literature, *On liberty, “The only purpose for which power can be rightfully exercised over any member of a civilized society against his will is to prevent harm to others ([[4]](#endnote-4))”.* He also said, *“It is not the duty of the law to concern itself with immorality as such. It should confine itself to those activities which offend against public order and decency or expose the ordinary citizen to what is offensive or injurious (iv)”.* What actions or omissions should be restricted, criminalized and punished changes from time to time and has been debated and discussed over the years. For instance, most people may agree to criminalise murder, theft, sexual abuse of children, whereas most would oppose restrictions on members of a particular caste or community from living in a particular geographical area, or restrict the type of religion one may profess, whereas some may want to bring their own sense of morality into the law and may want restrictions on consensual homosexuality, bigamy, private use of pornography ([[5]](#endnote-5)). There is a distinction between laws designed to prevent harm and those used to enforce moral values, or those with morality having to do with rights and that having to do with ideals (v).

Joel Feinberg, (who wrote four volumes on the moral limits of criminal law critiques and whose theories have been criticized by many), rejected legal paternalism that placed persons well-being above their autonomy, protecting them even from voluntarily accepted harm ([[6]](#endnote-6)). According to Feinberg, law should be used for protection of particular values, like personal autonomy and respect for the persons (v). His central question was whether choices made by people were voluntary or not, and he recommended a complex set of factors – (a) the more risky the conduct the greater degree of voluntariness required, if to be permitted; (b) the more irrevocable the risked harm, the greater degree of voluntariness required, if to be permitted (vi). He also stated that judgments of voluntariness will vary depending on background assumptions, the contexts and the purpose of the judgments (vi). Feinberg’s harm principle argument is that wrongdoing is nullified by consent, as in the case of euthanasia and gladiatorial battles, but the criminal law can be invoked where it is difficult to determine the genuineness of consent (v).

*Magnitude of harm*

Consent to being harmed does not mean that the magnitude of harm can be severe. If the harm inflicted is irreversible or leads to death or to spread of disease, consent would be irrelevant ([[7]](#endnote-7)). Those who believe that the magnitude of harm can set a limit to consent endorse the view that if the aggregate harm done to a person exceeds a certain magnitude and is greater than the good it should not be allowed (vii). If such a view is considered, then it may be permissible with the consent of a person to do more good than harm, but below a certain magnitude (vii). Sometimes it may be permissible to harm a person with their consent for the sake of good that is done to another person, as when rescuing another person.

However, the wrongness of harming a person with consent is derived from the fact that it is morally wrong for a person to consent to being harmed herself/ himself to a certain degree for the sake of a certain goal (vii). Some people also believe that we have moral demands that are irreducible to the demand to protect and promote goodness, that is, it is wrong to harm a person as a means to a greater good, and that is so even though harming a person promotes greater good (vii). Respect for autonomy of others does not permit harming a person as a means to a greater good in all circumstances (vii).

**Consent to bodily harm**

The moral, ethical questions that arise are whether consent to harm can be a defense to an act that would otherwise be a criminal wrongdoing? Does consent override prima facie wrong doing or is consent vitiated?

Consent is a defense for certain acts or omissions that would otherwise be an offence under the criminal law. Crimes of rape, sexual assault, medical interventions, etc. require that the victim did not consent, for if there was consent, then the action would be rendered lawful. Consent needs to be given by a person with capacity to consent (adult of sound mind), and could be expressed or implied, genuine – in the sense that the person giving consent comprehends the nature of the act, and consent is not vitiated by fraud, misrepresentation, mistake, coercion, undue influence, etc. Consent has been described as a defense to assault, but, in one sense, it is the failure of the prosecution to prove beyond reasonable doubt one of the elements of an offence (viz. absence of consent) ([[8]](#endnote-8)).

*Case law*

As a matter of public policy, a person cannot consent to being harmed. Thus, if two people agreed to have a fist fight, whether in public or private, that could inflict actual bodily harm, their consent would not be recognized in law, and their actions would be unlawful ([[9]](#endnote-9)). There are certain exceptions, such as a game of boxing (vii), reasonable medical interventions (where if there is no consent it could incur criminal liability) (viii), body piercing and tattooing ([[10]](#endnote-10)), rough and undisciplined horseplay ([[11]](#endnote-11)) and more recently in India, passive euthanasia ([[12]](#endnote-12)).

The courts have also weighed the possibility of consent to risk of unintentional bodily harm as in a game of rugby where a player was punched in the face fracturing a jaw, and though physical contact involving the use of force was necessary in the game, public policy imposed limits on the violence to which a rugby player can consent and force used outside the course of the game would lead to conviction ([[13]](#endnote-13)). Courts have considered the issue of consent or genuine belief (where there was no consent) to acquit persons who jokingly tossed two schoolboys in the air and allowed them to fall on the ground, causing grievous bodily harm (x) and where in jest some officers tried to ignite fire resistant suits, that led to serious burns, although it was not intended ([[14]](#endnote-14)).

Thus, certain acts that caused harm unintentionally or under a genuine belief that it would not cause harm, but did cause harm, have been looked upon by the courts moderately. However, Feinberg’s principle of autonomy that allowed a person to consent to harm without rendering it an actionable wrong, was not supported by the majority in the judgment of *R v. Brown* wherein it was held that since actual bodily harm was intended and caused, consent was irrelevant ([[15]](#endnote-15)). In *R v. Dica* the court held that consent to risk can be a defense, though, it was stated that, once a person has knowledge of the risk of transmission of a disease, s/he is unlikely to consent ([[16]](#endnote-16)).

**Duty**

Moral duties have correlative rights. Thus, just as there is a duty not to harm, there is a correlative right not to be harmed (vii). The question that arises is that can such a right be waived? Each person has a duty to protect and promote well-being. Absolute rights cannot be waived, because in harming one’s own self the right is violated (vii). Even if suicide is no more a criminal offence, it does not mean that society has accepted or consented to the practice of suicide, it has only de-criminalised it, but is yet concerned with the person with suicidal tendencies and needs to reach out to the person to prevent harm on the self.

In clinical trials, it is the duty of the researcher not to harm even though there is consent. It is not just a legal duty, but also a moral and ethical duty, and for the sake of advancement of science, would it be justifiable for a researcher to cause harm, albeit in a controlled setting, to healthy volunteers consenting to harm? Would it not tantamount to a breach of duty, especially of a researcher (or doctors) to save life, to prevent harm, to reduce pain and disease, to make people healthier – not sick? But, the argument can well be stated that in order to reduce disease in the population, research needs to be conducted in which a few people willing to take the risk of harm (minimal) for a greater public good. The question then arises is whether the consent was informed, complete, voluntary, not under coercion or undue influence or inducement, and was it an autonomous decision of the participant?

**Criminal law and consent**

Consent forms an important part of all clinical trials on human participants. The requirement under law and in all guidelines on clinical trials is that informed consent needs to be taken, where the participants are informed for the risks and benefits of the trial, alternatives, known risks and possibility of unknown risks, etc. The main difference between CHIM trials and Phase I – III clinical trials is that in the latter there are risks of harm (that may or may not occur), whereas, in the former there is intentional harm, though it is controlled and perhaps managed. It is not just a risk; it is actual harm that intentionally infects a healthy person with a disease.

Criminal law and public health laws contain many provisions that criminalise negligent and malignant spread of disease dangerous to life ([[17]](#endnote-17)). Under section 269 of the Indian Penal Code (IPC), *“Whoever unlawfully or negligently does any act which is, and which he has or has reason to believe to be, likely to spread the infection of any disease dangerous to life, shall be punished with imprisonment of either description for a term which may extend to six months, or fine or both.”* Section 270 penalizes the malignant spread of the infection that attracts a punishment of two years. Diseases like chicken pox, cholera, diphtheria, enteric group fevers, influenza pneumonia, leprosy, measles, plague, poliomyelitis, relapsing fever, scarlet fever, small pox, tuberculosis, typhus, yellow fever, etc. are diseases that are listed as “dangerous diseases” in public health laws and Municipal laws of States (xvii), that the State government shall have the power to contain their spread. CHIM trials may be conducted for such diseases termed as dangerous diseases in law, and that would then invoke unlawful, negligent or malignant spread of disease dangerous to life.

There are other provisions in the IPC such as those that criminalise voluntarily causing hurt, grievous hurt, or doing acts that endanger life and personal safety of others ([[18]](#endnote-18)) that could probably be of some relevance with regard to CHIM trials. The IPC defines the term “voluntarily” where a person is said to cause an effect voluntarily when it is caused by means whereby s/he intended to cause it or by means which s/he knew or had reason to believe to be likely to cause it ([[19]](#endnote-19)) and defines “injury” to denote any harm illegally caused to a person, in mind, body reputation or property ([[20]](#endnote-20)).

Criminal law to be invoked requires *mens rea* (guilty mind), knowledge and intention to harm. On the face of it, CHIM trials have all these elements that could invoke criminal law against the researchers, even though the true intention is the advancement of science. However, the exception of consent could be a defense for the researcher. Criminal law also shows leniency for acts done in good faith or that were not intended or known to cause harm or injury or done without criminal intent to cause harm ([[21]](#endnote-21)). The explanation given in law is that it is a question of fact in a case whether the harm to be prevented or avoided was of such a nature and so imminent as to justify or excuse the risk of doing the act with the knowledge that is was likely to cause harm ([[22]](#endnote-22)). In CHIM trials, though the exceptions in criminal law could come to the rescue of the researcher, the researcher may need to also provide reasons for the imminent need to take risk of doing an act that is likely to cause harm.

Taking informed consent prior to enrolling a person in a CHIM trial, would have to stand the test of whether a person can consent to being harmed (which the court in *R v. Brown* has said that consent would be irrelevant, and harm would be measured), and while consenting how much knowledge did the participant have on the harm that would be inflicted, and after knowing the extent of harm, was the consent voluntary, not under any undue influence, misrepresentation, etc. and was informed. If we follow Feinberg’s principle, then the participant’s autonomy and consent to enter the trial would supersede, what he called, the legal paternalistic role of law that would prevent harm even on consenting adults. The magnitude of the harm would also need to be measured to make consent relevant in CHIM trials.

Another important aspect for consideration is that the value of a person’s moral autonomy and interests each provide a restriction on self-harm, which then would necessarily, provide some limits on what others may do even if consent to harm was obtained (vii).

**Compensation**

The WHO guidance document states that the information gained should clearly justify the risks to human participants and that “*it is essential that challenge studies be conducted within ethical framework in which truly informed consent is given”*(i). The qualification of “truly” informed consent seems to suggest that informed consent taken for clinical trials is not truly informed consent, which is required for CHIM trials.

But, is informed consent enough to allow CHIM trials? There does not appear to be much documentation on the high amount of compensation given to healthy participants to enroll for CHIM trials. Providing a good amount of compensation would be justified in one sense, as a healthy person would be taking a grave risk of being infected with a disease that would probably have some short term and probably some long term adverse effects on her/his good health. But, in another sense, would providing high compensation be an inducement for persons to take the risk of harm? What is the true meaning of respect and dignity of the individual human participant, who agrees to be harmed and to take the risk of harm for the sake of science and is then faced to battle with temporary or reversible harm or permanent harm?

**Conclusion**

Laws are designed to prevent harm and are to do with the morality of rights of people. The Constitutional morality respects every human being and reaches to provide all persons to lead healthy and dignified lives. The right to life and liberty guaranteed under Article 21 of the Constitution of India includes the right to health that includes the highest attainable standard of health. Autonomy of individuals needs to be respected and self-harm may be allowed in certain exceptional situations, such as in the case of euthanasia.

Research experiments on humans have been blotted with scandals and violations of rights of participants. The small pox trial in 1796 ([[23]](#endnote-23)), the Nuremberg trials that included freezing experiments, hypothermia trials, twin experiments, wound experiments, tuberculosis experiments, etc. where involuntary participants were forced to undergo the torturous experiments ([[24]](#endnote-24)) have led to development of ethical principles in conducting human trials. Could such trials be justified had informed consent been taken and if they were voluntary?

By allowing CHIM, are we reinforcing the paternalistic nature of science and slowly moving back in time? In a country like India, where we know that medicine and healthcare are still highly paternalistic, and consent is just a routine procedure (where it is not absent), where poverty is rampant, hand-picked persons can give ethical approvals and money can buy anything (even research participants), can we allow CHIM with our eyes fully open on the possible consequences in this country? Clinical trial participants are unable to seek redress for their grievances; justice is not seen to be provided to the victims of clinical trials, with cases pending for years and no respite to participants. There is no comprehensive law that protects the rights of clinical trial participants, (with the exception of providing compensation for trials conducted for new drugs); and it is well known that most participants enroll in clinical trials not only for altruistic reasons but also for earning some money that would provide for their families.

The question, therefore, is not whether we should do research or not, but how much have we learnt from the past, and what safeguards have we brought to protect participants in research? Are we in a developing country, like India, getting induced to do CHIM, so that it would probably help build a healthcare infrastructure? In the name of controlling diseases by understanding their progress and developing vaccines, are just finding easy ways to prevent diseases, rather than concentrate our efforts on hygiene and sanitation, providing nutrition and food to those in need.

It is important to set a high threshold if we are to protect the cardinal right to autonomy, dignity and wellbeing of individuals. We also need to do a reality check on not just the magnitude of the harm but also the voluntariness of informed consent. Maybe, the time has come rethink consensual harm doing.

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2. Yan, Wudun, *“Challenge Accepted: Human challenge trials for dengue”*, Nature Medicine, Vol.21, Number 8, August 2015, pages 828- 830 [↑](#endnote-ref-2)
3. Vora, P, “*Interview: What safeguards does India need before it can move to a faster way of developing drugs?”* Scroll.in, Feb. 15, 2018. Available at <https://scroll.in/pulse/868784/interview-is-india-ready-to-safely-adopt-a-faster-way-of-developing-medicines>. Last accessed on 6.4.2018 [↑](#endnote-ref-3)
4. Mill, J.S., *On Liberty,* (London, 1859), Chapter I [↑](#endnote-ref-4)
5. Dworkin, Gerald, *“Morality, Harm and the Law”*, University of Illinois at Chicago, 1994, Chapter 1: Introduction, page 2 [↑](#endnote-ref-5)
6. Book Review – Bayles, Michael, “*Harm to Self: The Moral limits of criminal law, Vol.3 by Joel Feinberg”,* Law and Philosophy, Vol.7, No.1 (Apr.1988), pp.107-122. Available at <http://www.jstor.org/stable/3504624> [↑](#endnote-ref-6)
7. Tadros, Victor, *“Consent to Harm”* Current Legal Problems, Vol. 64 (2011) pp. 23-49 [↑](#endnote-ref-7)
8. Devereux, John A., *“Consent as a defence to assaults occasioning bodily harm – The Queensland Dilemma”,* The University of Queensland Law Journal, Vol.14, No. 2, pp. 151-159 [↑](#endnote-ref-8)
9. *Attorney-General’s Reference* (No.6 of 1980) [1981] 2 All ER 1057. Also see *R v Coney* (1882) 8 Q.B.D. 534 [↑](#endnote-ref-9)
10. *R v. Wilson* (1996) Times Law Report, March 5, 1996 [↑](#endnote-ref-10)
11. *R v. Jones (Terence)* (1986) 83 Cr. App. R 375 [↑](#endnote-ref-11)
12. *Common Cause v. Union of India & anr.*, Supreme Court of India, Writ Petition (Civil) No. 215 of 2005, judgment dated 9.3.2018 [↑](#endnote-ref-12)
13. *R v. Billinghurst* [1978] Crim LR 553 [↑](#endnote-ref-13)
14. *R v. Aitken & ors.* [1992] 1 WLR 1066 [↑](#endnote-ref-14)
15. *R v. Brown & ors.* [1993] 2 All ER 75 [↑](#endnote-ref-15)
16. *R v. Dica* [2004] 3 All ER 593 [↑](#endnote-ref-16)
17. Sections 269 and 270 of the Indian Penal Code and State Municipal Council Acts like S.237 of the Maharashtra Municipal Councils, Nagar Panchayats and Industrial Townships Act, 1965; Tamil Nadu District Municipalities Act, 1920; Madras Public Health Act, 1939; Travancore Cochin Public Health Act, 1955; Goa, Daman and Diu Public Health Act, 1985 with Rules 1987 [↑](#endnote-ref-17)
18. Sections 319-323 and 336 of the Indian Penal code [↑](#endnote-ref-18)
19. Section 39 of IPC [↑](#endnote-ref-19)
20. Section 44 of IPC [↑](#endnote-ref-20)
21. Sections 81, 87, 88, 92, 95 of IPC [↑](#endnote-ref-21)
22. Explanation to Section 81 of IPC [↑](#endnote-ref-22)
23. Riedel, Stefan, *“Edward Jenner and the history of small pox and vaccination”*, Proceedings (Baylor University Medical Centre) 2005 Jan; 18(1): 21-25. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1200696/>, last accessed on 9.4.2018 [↑](#endnote-ref-23)
24. See <http://www.jewishvirtuallibrary.org/the-ethics-of-using-medical-data-from-nazi-experiments> [↑](#endnote-ref-24)