

past, and what safeguards we have brought in to protect participants in research. Are we, in a developing country like India, getting induced to perform CHIM studies, seeking to help build a healthcare infrastructure? In the name of controlling diseases by understanding their progress and developing vaccines, are we just looking for easy ways to prevent diseases, rather than concentrating our efforts on hygiene and sanitation, providing nutrition and food to those in need? There does not seem to be any imminent need to conduct CHIM trials in India. The scarce resources need to be optimally utilised to strengthen primary healthcare and the social determinants of health that are the fundamental and basic rights of all humans.

It is important to set a high threshold if we are to protect the cardinal rights to autonomy, dignity and wellbeing of individuals. We also need to reconsider the sophistry of consent that allows harm and do a reality check on not just the magnitude of the harm but also the voluntariness of informed consent.

**Note**

<sup>1</sup> State Municipal Council Acts like the Maharashtra Municipal Councils, Nagar Panchayats and Industrial Townships Act, 1965, s. 237; 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.

**References**

1. Expert Committee on Biological Standardization. Human challenge trials for vaccine development: regulatory considerations. Geneva:WHO; 2016 [cited 2018 Oct 9]. Available from: [http://www.who.int/biologicals/expert\\_committee/Human\\_challenge\\_Trials\\_IK\\_final.pdf](http://www.who.int/biologicals/expert_committee/Human_challenge_Trials_IK_final.pdf)
2. Yan W. Challenge accepted: Human challenge trials for dengue. *Nature Medicine*, 2015 Aug; 21(8): 828- 30.
3. Bamberg B, Selgelid M, Weijer C, Savulescu J, Pollard AJ. Ethical criteria for human challenge studies in infectious diseases. *Public Health Ethics*.

- 2016;9(1):92-103.doi:10.1093/phe/phv026.
4. Gopichandran V. Controlled human infection model for vaccine development: Zika virus debate. *Indian J Med Ethics*. 2018 Jan-Mar; 3(1) NS: 51-5.DOI: 10.20529/IJME.2017.093.
5. United Nations Educational, Scientific and Cultural Organisation. Universal Declaration on Bioethics and Human Rights. Geneva: UNESCO;2005 Oct 19 [cited 2018 Oct 8]. Available from:[http://portal.unesco.org/en/ev.php-URL\\_ID=31058&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html)
6. Mill JS. *On Liberty*. 3<sup>rd</sup> edition. London: Longman;1864. Chapter I.
7. Dworkin G. *Morality, harm and the law*. Chicago: University of Illinois;1994, Chapter 1: Introduction, pp 1-5.
8. Bayles MD. Book review: *Harm to self: The moral limits of criminal law*. *Law and Philosophy*. 1988 Apr; 7 (1):107-22. Available from: <http://www.jstor.org/stable/3504624>
9. Tadros V. Consent to harm. *Current Legal Problems*. 2011 Jan 1; 64(1): 23-49.
10. Devereux JA. Consent as a defence to assaults occasioning bodily harm – The Queensland dilemma. *Univ Qld Law J*. 1987;14(2):151-9.
11. *Attorney-General's Reference* (No 6 of 1980) [1981] 2 All ER 1057.
12. *R v Wilson* (1996) Times Law Report, March 5, 1996.
13. *R v Jones* (Terence) (1986) 83 Cr. App. R 375.
14. *Common Cause v Union of India & Anr*. Supreme Court of India, Writ Petition (Civil) No. 215 of 2005, judgment dated March 9, 2018.
15. *R v Billingham* [1978] Crim LR 553.
16. *R v Aitken & Ors*. [1992] 1 WLR 1066.
17. *R v Brown & Ors*. [1993] 2 All ER 75.
18. *R v Dica* [2004] 3 All ER 593.
19. Resnik DB. Exploitation in biomedical research. *Theor Med Bioeth*, 2003 Feb; 24(3):233-59. DOI:10.1023/A:1024811830049.
20. Government of India. Indian Penal Code, 1860. Act 45 of 1860. Delhi: Gol; Oct 1860 [cited 2018 Oct 16]. Available from: <http://www.advocatekhoj.com/library/bareacts/indianpenalcode/index.php?Title=Indian%20Penal%20Code,%201860>
21. Riedel S. Edward Jenner and the history of small pox and vaccination. *Proc (Bayl Univ Med Cent)*. 2005 Jan [cited 2018 Oct 16]; 18(1):21-5. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1200696/>
22. Cohen BC. Nazi medical experiments: The ethics of using medical data from Nazi experiments. *Jewishvirtuallibrary.org*. Available from: <http://www.jewishvirtuallibrary.org/the-ethics-of-using-medical-data-from-nazi-experiments>

## Public engagement in the context of a CHIM study

MANJULIKA VAZ

**Abstract**

Public engagement especially in new and contested areas of medical research is an essential ethical requirement. It helps to build trust, to embed ethical discourse in public beliefs and values and widen the accountability and the governance of biomedical research. Historically, ethical codes resulted from public protest following unethical medical research practices. Unethical

practices do continue to a certain extent, primarily among unempowered communities. The need for public awareness, public deliberation and public advocacy are even more important in a country like India, where “research” is not understood, where paternalism on the part of the health professional, and the non-questioning attitude of the patient/participant have been customary, followed in recent times, by mistrust and an expectation of corruption in the public mind when dealing with a healthcare set up.

CHIM studies carry various levels of unknowns. There are challenges of public non-comprehension of the need for being “infected”; of families and communities being at risk; of possible high levels of compensation being offered as inducements; of other public health / preventive measures being supplanted. It is important for researchers and regulators in India, not to rush into

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*implementing such studies but to first engage with the public, listen to their concerns; and initiate deliberative mechanisms for public – researcher dialogue; and invest in public advocacy.*

### **Public engagement as an ethical requirement**

Over the last two decades there has been a “participatory turn” in the understanding of science, technology and ethics (1, 2). Ethical reasoning is seen not to be in the realm of “experts” alone, but also derived from public and social engagement. This has its roots in the deliberative concepts of Discourse Ethics of Habermas and perceptions of “common good” (3,4). Public engagement in the ethical discourse thus involves understanding values, views and experiences of the public and noting the divergence in perceptions between “those who decide and those who are affected by decisions” (1). This is beyond the notion of “community engagement” for creating awareness about health or science matters. Public engagement is in essence, a two-way dialogue with policy makers and scientists on scientific advancements and addresses areas of “public trust deficit” (5).

Interactions with the public on biomedical research, the benefits of participation, and the rules and bioethical guidelines that exist to protect their interests will likely create a more empowered public. This enables a wider base of governance of biomedical research and a greater accountability to society, as seen for example in biobanking research (6). It is also important that ethics regulations evolve “bottom up” and are not exclusively “expert based”, as the latter risks being “one-sided, biased or ideological—thus illegitimate” (1). Listening to the voices of the people also ensures that the notion of “public good” encompasses multiple perspectives and standpoints. A key outcome of public engagement is a greater transparency of purpose and procedures, the ability to understand and to predict ground level problems at the individual and societal levels, identification of issues of vulnerability and methods to address them (7), addressing of fears and concerns of possible risks of participation in biomedical research, and most importantly, the building of trust between the scientific community and the public (8). Public engagement thus improves people’s participation, trust and confidence in the researcher, and understanding of the safeguards that exist. Public engagement in the development of the rules and bioethical guidelines that protect their interests also establishes the public as a key stakeholder (9).

### **Ethical issues with biomedical research and public outcry**

Historically, ethical guidelines developed after critical unethical events took place and resulted in a public outcry. In the early 1930s, the Lübeck disaster where 72 deaths occurred when 251 neonates were orally given three doses of the new Bacille Calmette–Guérin (BCG) anti tuberculosis (TB) vaccine contaminated with *Mycobacterium tuberculosis* drew public attention to medical experimentation on human beings and resulted in widespread criticism of medical professionals (10). At this time, Ludwig Fleck, a medical microbiologist

and a philosopher of science, wrote extensively on the dilemmas of modern medical experimentation on human beings and the wellbeing of individuals. His approach was different from the existing approach of scientific reasoning and ethical regulations. He attempted to promote a more democratic understanding of science, the initiation of “thought collectives” to deliberate scientific advancements of the time and to ensure a “public information campaign” where scientific facts and uncertainties (in this case the controversies on the BCG vaccine) were communicated to people (11). At the heart of Fleck’s arguments was the idea of the strong social dependence of all knowledge.

The German Guidelines on Human Experimentation, 1931 (Reich Health Council Regulations) were formulated in response to this (12). An interesting fact is that these were at odds with Nazi research practices. Unethical Nazi experimentation, including use of infectious agents, on captives in concentration camps led to extensive court trials and, ultimately, the formulation of the Nuremberg Code in 1948. Similarly, the unethical Tuskegee experiments in the USA on understanding syphilis (from 1932) ended in 1972 following a public outcry. This resulted in the setting up of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1974 and the Belmont Report in 1979 (13).

### **What are public concerns with biomedical research?**

The general public in developing countries, especially communities with limited familiarity with English, do not comprehend the word “research” (8, 14,15) and this often translates variably in local languages. An encounter with a physician is typically perceived as therapy. “Therapeutic misconception” therefore results in a low appreciation of the risks involved in experimental interventions (16). This is compounded by the trusting patient-doctor relationship, the paternalistic approach of physicians towards their patients and the power imbalance in the encounter. This, of course, reflects the norms and values of the culture and the society in which this encounter is embedded (17).

Lay people with some knowledge of medical research, even in India, have expressed their concerns about things going wrong, about the misuse of research, about the motives of the doctor-researcher, commercial involvement and commercial exploitation of research (8). The process of taking informed consent, which is expected to empower research participants and respect their autonomy in choosing whether to participate or not, was seen by the public as protecting the interest of the doctor and the hospital more than their interests (8). Persons from the lower socio-economic strata also feared anything given “free,” as it was associated with poor quality and doubtful intent (8). Participants in research are also fearful that they will be forgotten after the research is completed, and that findings which might concern them or their children will not be shared with them (18,19,20). On the other hand, community-based participatory research (CBPR) practices have been successful in involving

community members (including those affected by the issue being studied), organisational representatives, and academic researchers. These practices ensure ownership of the research process and outcomes, and grounding of the translational priorities and policy decisions in social realities (21, 22).

### Uncertainties in the context of Controlled Human Infection Model (CHIM) studies

The purpose of a CHIM study is to intentionally infect healthy human volunteers and cause disease, which sets it apart from traditional clinical trials (23). This also appears to fly in the face of the principle "*primum non nocere*" ie "first, do no harm," also embodied in Principlism as "non-maleficence". People conducting CHIM studies attempt to reduce risk through several means – they use well characterised strains for which the clinical course is generally well understood and for which there are effective treatments, and also target healthy volunteers who are least likely to develop problems. However, this is not always possible. For instance, in the case of the Zika and Ebola virus infections, there are no known cures and the treatment is only symptomatic. Sometimes, infections may be associated with rare but significant complications. As an example, in the case of Zika virus there is the possibility of acquiring Guillain-Barre syndrome (GBS), a severe neurological disorder due to immunological problems caused by the Zika virus (24). In these situations, the grading of risk will understandably be higher.

Some of the concerns about CHIM studies are a result of abuses that have occurred historically, some involving scientists of considerable repute. Armauer Hansen, for instance, the discoverer of *M. leprae* tried to inoculate the eye of a woman with material drawn from a leprosy patient without her consent, in attempt to demonstrate Koch's postulates (25). Albert Neisser, the second most celebrated German scientist (after Koch) at the time, and the discoverer of *N. gonorrhoea*, injected women prostitutes with serum from those suffering with syphilis in an attempt to evaluate the efficacy of serum therapy in syphilis. While these are not typical CHIM studies in the way CHIMS are designed today, these and other historical episodes contributed to an overwhelming fear of exploitation, and a sense that such research was unnatural and unethical (26). It is a fact that these episodes, unacceptable as they were, strengthened the resolve of people and researchers to prevent unethical research.

Another relevant concern in CHIM studies is that of the volunteer comprehending the process of getting infected, developing low risk infection, the importance of confinement, reporting of symptoms and adherence to treatment. This requires a paradigm shift from informed, legalistic consent to empowered, understood consent. The fact that populations may be illiterate or poorly educated, belong to socially disadvantaged communities, and even if educated have poor "health literacy" are significant challenges. Yet, these may also be the populations where the diseases are most prevalent and which are most likely

to benefit from the research. From an ideological point of view, CHIM studies, and their translatory products, may sometimes be seen as an inadequate salve for deficiencies in the provision of essential facilities such as sanitation, clean drinking water, and improved food hygiene and nutritional practices, among others. While proponents of CHIM studies will argue that their studies do not offset the need or desire to address the social determinants of health, opponents will see these studies as doing precisely that – promoting immediate focussed solutions at the expense of longer term, broader benefits.

The ultimate aim of a CHIM or challenge study is to make drug development pathways more efficient, less costly, and to test vaccine candidates in the country where the diseases are most prevalent and where patients are most likely to benefit from the intervention (27). The need for local CHIM studies is important since local/regional factors and the biological variability in different populations can alter host-pathogen dynamics, and make extrapolations of results from one population to another more difficult. The assessment of preliminary drug or vaccine efficacy could show that a vaccine candidate is likely to be ineffective thereby preventing unnecessary exposure of thousands of people in large phase III trials.

There are specific uncertainties or ethical dilemmas for CHIMs.

1. An individual is put at low, medium or high risk, with no direct individual benefit.
2. In the infectious state, the community may also be exposed to risk.
3. Several unknowns such as the duration of the infectious state, the modes of infection etc., make the period of quarantine difficult to define. Extended quarantine raises an ethical issue of prolonged, unnecessary confinement and shorter quarantines could enhance risk to family and social circles.
4. In the context of India and other developing country settings, there is a need to identify a true "volunteer" as someone who primarily:
  - comprehends the risk and will follow the controlled regimen;
  - has sufficient health literacy to consent to the risk;
  - comes from the setting where the infection is generally prevalent;
  - is found to be "healthy after being screened– clinically and serologically;
  - can freely question the physician / researcher without fear, during the consent process;
  - has the potential and means to benefit from any therapies developed through the study.
5. Compensation needs to be fair but not unduly large. Would disclosure of compensation be an inducement for a healthy volunteer?

6. The study of the infective agent and its control needs to be of extreme public health / national health importance. Who makes this decision? The purpose of social benefit / public health/ greater good needs to be truly understood. Do the ends justify the means? Is it right to volunteer?

There is scarce bioethical literature currently available to guide researchers and research ethics committees in navigating the complex ethical issues of purposefully infecting healthy volunteers. The scholarly article by Bamberg et al in 2016, suggests four requirements for human challenge studies to be ethical "(i) conduct independent expert reviews, including systematic reviews; (ii) ensure a publicly available rationale for the research; (iii) implement measures to protect the public from the spread of infection beyond the research setting; and (iv) develop a new system for compensation for harm" (28).

### Public engagement in the context of CHIMs

In a CHIM study, the primary stakeholders would be the scientists, the medical doctors, the government regulator, probably the institutional ethics committee and the communities from which volunteers will be recruited. The main objective of public engagement is for all the stakeholders involved to understand each other and for all to understand the concerns and doubts and expectations of the key stakeholder, which is the public. This will ensure that the ethical guidelines for CHIM studies in India take into consideration the lived experiences and beliefs of communities in India. The starting point needs to be the sharing of the ethical compulsions of conducting a CHIM from a medical perspective and the ethical dilemmas from a participant / community perspective, as spelt out above. What follows is a guided deliberation and facilitated negotiations so that power imbalances are realigned and subaltern voices are amplified. It will also not limit the construct of ethics to individuals but include a social component, as CHIM studies have a public health component which needs public deliberation. Not only will this be in the public interest but it will also help the researchers in the acceptance, participation and understanding of CHIM studies and continuity in the generation of knowledge. The HPV vaccine trials in India show that any procedural or ethical lapses result in high levels of mistrust among the public and the medical researcher / medical community (29,30), and a stoppage of the research.

Public engagement is desirable at three levels:

1. Evaluation of the "public voice" through in-depth interviews with different sections of society, focussed group discussions with homogeneous groups of people on the key ethical areas, and public opinion surveys
2. Public education and advocacy where technical information on the purpose of CHIM studies, the inability to do such studies in animals or *in vitro*, and the roles of ethics committees as supervisory and regulatory bodies, is explained in lay person's language without being simplistic.
3. Public deliberation through town hall meetings / citizen juries / science cafes (similar to Fleck's "thought

collectives") where the subject experts present the purpose, procedures and other scientific facts about a CHIM study as well as areas that are uncertain, followed by small group deliberation on specific questions. This allows for development of consensus as well as debate about contentious issues. Public deliberation is a structured process and an optimal methodology for discussion of newer areas and practices in health research. It allows for informed opinions, engagement in debate and arrival at collective decisions (31, 32,33). It goes beyond a process of symbolic consultation, and fits in well with Rawls' publicity principle and his notion of "reasonable citizens."

In addition, specific CHIM studies will benefit from "multi-stakeholder regulatory structures" which have been used in other contexts such as genetic research and biobanking research to ensure transparency and accountability (6). CHIMs are truly "challenge" studies, where ethical issues are complex and dynamic, both in terms of the diseases being studied as well as the social contexts where they are being carried out. A one-size-fits-all philosophy does not exist for the ethics of CHIM studies nor can the same ethical regulations used for clinical trials of new drugs or devices be applicable. The levels of the unknown, of risk and subsequently of harm, appear to set such studies apart.

Public engagement is not without its issues (34). Some may question whether the Indian public is ready for this highly engaged mode of working with scientists, doctors and government regulators, whether Ethics Committees are ready to modify their functioning to take on a more engaged mode of working with the public, and whether government agencies and funders of such research will invest the time and money for public engagement. These questions, while relevant, cannot be reasons for non-engagement with the public. It might only raise the question whether India is ready for CHIMs or not.

A vibrant public, aware of its rights, and of medical advancements aimed at public good, as well as the opportunities to engage with regulators and the researcher community, is not a threat but a critical resource to ensure not only the acceptance and sustainability of research but the formulation of an inclusive ethics that values the public voice. In the words of Roger Chennells, his work as a human rights lawyer for the San communities of southern Africa, and the exploitative research done on them, was grounded in "applied philosophy and public ethics" and embedded in "community consultations and negotiations" (35). Hence, public engagement for a CHIM study should be a pre-requisite and not an option. The philosophy of communitarian, discourse ethics with a public health focus needs to drive the ethical debate in India.

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## References

- Schicktanz S, Schweda M, Wynne B. The ethics of 'public understanding of ethics'—why and how bioethics expertise should include public and patients' voices. *Med Health Care Philos.* 2012 May;15(2):129–39
- Burgess M.M. From 'trust us' to participatory governance: Deliberative publics and science policy. *Pub Underst Science.* 2014 Jan; 23(1): 48 – 52.
- Rehg W. *Insight and solidarity: The discourse ethics of Jürgen Habermas.* Berkeley and Los Angeles: University of California Press; 1997. p 281.
- Bialobrzeski A, Ried J, Dabrock P. Differentiating and evaluating common good and public good: Making implicit assumptions explicit in the contexts of consent and duty to participate. *Public Health Genomics* 2012;15(5):285–92.
- Wynne B. Public engagement as a means of restoring public trust in science – Hitting the notes, but missing the music? *Community Genet* 2006; 9:211–20. <https://doi.org/10.1159/000092659>
- Kaufman DJ, Murphy-Bollinger J, Scott J, Hudson KL. Public opinion about the importance of privacy in biobank research. *Am J Hum Genet A.* 2009 Nov; 85(5): 643–54.
- London L. Ethical oversight of public health research: Can rules and IRBs make a difference in developing countries? *Am J Public Health.* 2002 Jul; 92(7):1079-84.
- Vaz M, Vaz M, Srinivasan K. Listening to the voices of the general public in India on biomedical research – an exploratory study. *Indian J Med Ethics.* 2015 Apr-Jun; 12(2): 68-77.
- Blom E, De Vries R. Towards local participation in the creation of ethical research guidelines. *Indian J Med Ethics.* 2011 Jul-Sep; 7(3):145-7.
- Fox GJ, Orlova M, Schurr E. Tuberculosis in newborns: The lessons of the "Lübeck Disaster" (1929–1933). *PLoS Pathog.* 2016 Jan; 12(1):e1005271. <https://doi.org/10.1371/journal.ppat.1005271>
- Bonah C. Experimental rage: the development of medical ethics and the genesis of scientific facts Ludwik Fleck: an answer to the crisis of modern medicine in interwar Germany? *Soc Hist Med.* 2002 Aug; 15(2):87–207
- German guidelines on human experimentation 1931. In: Reich WT, editor. *Encyclopaedia of Bioethics*, 2nd Edition. New York: Macmillan; 1996 [cited 2018 Mar 20]. Appendix p. 2762–3. Available from: [http://artandersonmd.com/1931\\_german\\_hu\\_guidelines.html](http://artandersonmd.com/1931_german_hu_guidelines.html)
- Department of Health, Education, and Welfare. 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, 1979 [cited 2018 Oct 20]. Available from: <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html>
- Van Alphen IAS, Engel N, Vaz M. Local perspectives on universal bioethics—A qualitative study on informed consent in South India. In: Engel N, Hoyweghen IV, Krumeich A, editors. *Making global health care innovation work: Standardization and localization.* New York: Palgrave Macmillan; 2014. p. 41–79.
- Zaman S, Nahar P. Searching for a lost cow: ethical dilemmas in doing medical anthropological research in Bangladesh [Internet]. *Medische Antropologie.* 2011 [cited 2017 Apr 3]; 23(1):153–63. Available from: [http://tma.socsci.uva.nl/23\\_1/zamannahar.pdf](http://tma.socsci.uva.nl/23_1/zamannahar.pdf)
- Bamberg M, Budwig N. Therapeutic misconceptions: when the voices of caring and research are misconstrued as the voice of curing. *Ethics Behav.* 1992; 2(3):165–84.
- Hannay DR. *Lecture notes in Medical Sociology*, Oxford, UK: Blackwell Scientific Publications, 1988.
- Fernandez CV, Bouffet E, Malkin D, Jabado N, O'Connell C, Avard D, Knoppers BM, Ferguson M, Boycott KM, Sorensen PH, Orr AC, Robitaille JM, McMaster CR. Attitudes of parents toward the return of targeted and incidental genomic research findings in children. *Genet Med.* 2014 Aug; 16(8):633–40.
- Roberts J.S, Shalowitz D.I, Christensen K.D, Everett JN, Kim SY, Raskin L, Gruber SB. Returning individual research results: development of a cancer genetics education and risk communication protocol. *J Empir Res Hum Res Ethics.* 2010 Sep; 5(3):17–30.
- Vaz M, Vaz M, Srinivasan K. The views of ethics committee members and medical researchers on the return of individual research results and incidental findings, ownership issues and benefit sharing in biobanking research in a South Indian city. *Dev World Bioeth.* 2017; 1–10.
- Rhodes SD, Malow RM, Jolly C. Community-based participatory research (CBPR): A new and not-so-new approach to HIV/AIDS prevention, care, and treatment. *AIDS Educ Prev.* 2010 Jun; 22(3):173-183. doi:10.1521/aeap.2010.22.3.173.
- Viswanathan M, Eng E, Ammerman A, Gartlehner G, Lohr KN, Griffith D, Rhodes S, Samuel-Hodge C, Maty S, Lux L, Webb L, Sutton SF, Swinson T, Jackman A, Whitener L. Community-based participatory research: Assessing the evidence. *Evid Rep Technol Assess (Summ).* 2004 Aug; (99):1-8.
- Balasingam S, Horby P, Wilder-Smith A. The potential for a controlled human infection platform in Singapore. *Singapore Med J.* 2014 Sep; 55(9), 456-61.
- Gopichandran V. Controlled human infection models for vaccine development: Zika virus debate. *Indian J Med Ethics.* 2018 Jan-Mar; 3(1) NS: 51-5. DOI: 10.20529/IJME.2017.093. doi:10.11622/smedj.2014114
- Ghosh S, Chaudhuri S. Chronicles of Gerhard-Henrik Armauer Hansen's Life and Work. *Indian J Dermatol.* 2015 May-Jun; 60(3): 219–21.
- Pollard AJ, Savulescu J, Oxford J, Hill AV, Levine MM, Lewis DJ, Read RC, Graham DY, Sun W, Openshaw P, Gordon SB.. Human microbial challenge: the ultimate animal model. *Lancet Infect Dis.* 2012 Dec; 12(12): 903-5. doi:10.1016/s1473-3099(12)70292-x
- Gordon S B, Rylance J, Luck A, Jambo K, Ferreira DM, Manda-Taylor L, Bejon P, Ngwira B, Littler K, Seager Z, Gibani M, Gmeiner M, Roestenberg M, Mlombe Y; . A framework for Controlled Human Infection Model (CHIM) studies in Malawi: Report of a Wellcome Trust workshop on CHIM in Low Income Countries held in Blantyre, Malawi. *Wellcome Open Res.* 2017 Aug 24; 2:70. doi:10.12688/wellcomeopenres.12256.1
- Bamberg B, Selgelid M, Weijer C, Savulescu J, Pollard A J. Ethical criteria for human challenge studies in infectious diseases. *Public Health Ethics.* 2016 Apr; 9(1): 92–103. <https://doi.org/10.1093/phe/phv026>
- Sarojini N, Deepa V. Trials and tribulations: an expose of the HPV vaccine trials by the 72nd Parliamentary Standing Committee Report. *Ind J Med Ethics.* 2013 Oct-Dec; 10(4): 220-2.
- Ramanathan M, Varghese J. The HPV vaccine demonstration projects: We should wait, watch and learn. *Ind J Med Ethics* 2010 Jan-Mar; 7(1):43–5.
- Molster C, Maxwell S, Youngs L, Potts A, Kyne G, Hope F, Dawkins H, O'Leary P. An Australian approach to the policy translation of deliberated citizen perspectives on biobanking. *Public Health Genomics.* 2012; 15(2):82–91.
- O'Doherty KC, Hawkins AK, Burgess MM. Involving citizens in the ethics of biobank research: informing institutional policy through structured public deliberation. *Soc Sci Med.* 2012 Nov; 75(9):1604-11.
- Bombard Y, Abelson J, Simeonov D, Gauvin FP. Citizens' perspectives on personalized medicine: a qualitative public deliberation study. *Eur J Hum Genet.* 2013 Nov; 21: 1197–1201.
- Felt U, Fochler M, Müller A, Strassnig M. Unruly Ethics: On the Difficulties of a Bottom-up Approach to Ethics in the Field of Genomics. *Public Underst Sci.* 2008; 18: 354-71.
- Chennels RS. *Equitable access to human biological resources in developing countries: Benefit sharing without undue inducement.* Switzerland: Springer; 2016. p. 195.

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