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Tacit trust cannot be violated: report of the Presidential Commission for the Study of Bioethical Issues, USA

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Moral Science is the report and recommendations on current ethical standards for the protection of human subjects in research funded by the American government. The report was made public in December 2011. It was commissioned by the president of the United States – a move catalysed by the recent exposure of the ethical violations by American scientists in the study of syphilis among people in Guatemala from 1946 to 1948. American researchers enrolled Guatemalan people in a research study with the intention of exposing them to sexually transmitted diseases without informing them or seeking consent. The human subjects were mentally ill people, prostitutes, soldiers, and people suffering from epilepsy as well as terminal diseases. Relevant information was deliberately concealed from the subjects, the public and others who may have questioned their methodology and intentions. As a result of the flawed design and execution of this research, hundreds of Guatemalan human subjects were exposed to syphilis and gonorrhoea.

These findings have brought to the forefront several ethical issues around the conduct of biomedical research, particularly those using human subjects. The report thus evaluates prevailing standards in the US for the protection of human subjects, and makes recommendations to further strengthen the system. The study was conducted by a panel of international experts in bioethics and biomedical research from 10 countries. The review is the first of its kind undertaken by a national ethics commission in the past decade; this points to the necessity for revisiting ethical norms on a periodic basis, rather than assuming that the principles of ethics which currently guide us are sufficient and will remain constant for all time. This itself is significant since the process of periodic re-evaluation is in fact necessitated due to "challenges presented by novel scientific advances, a perceived mismatch between ethical principles and their implementation, or revelations of abuse" (1:4).

Although the review is of US government-funded research, its findings and recommendations are equally germane to private research in the US, as well as to both public and private research conducted internationally. Given that the US government-funded research is also carried out internationally, *Moral Science* is clearly an important document for many countries other than the US. Biomedical research is rapidly expanding internationally, and is increasingly directed towards diseases that are more prevalent in developing countries where there also is a higher incidence of treatment-naïve subjects. While acknowledging that this international paradigm in research is driven by reasons of cost efficiency as well as scientific and marketing purposes, the Commission requires the same ethical principles and recommendations to be followed by federally-funded projects abroad.

Of particular interest in this report is its firm moorings in well-known ethical principles and less familiar philosophical traditions, even while it pays token obeisance to theology. Together, these clearly set out, examine and reiterate the more fundamental underpinnings of ethical behaviour expected from medical researchers. Rather than reducing the report to make it concise by listing a series of discrete points, as may have been preferred by medical researchers, the report is discursive and presents its findings and recommendations by invoking various points of view and arguments, and using an array of largely philosophical positions to counter them. The language is deceptively simple and non-technical; the arguments startlingly complex. The report is thus worthy of being perused for the systematic approach it exemplifies, its lucidity as well as its complexity.

The report emphasises at the outset that public support and confidence are essential to the pursuit of biomedical research, and since the latter depends on human subjects for expanding its knowledge base, it is imperative that the tacit trust invested in researchers not be violated by them; otherwise, this would result in the loss of public confidence, which in turn would stall research and the growth of scientific knowledge. The report thus points out that it is this non-negotiable nature of biomedical research which requires it to be held accountable to the larger public. The usual rhetoric of sacrifices to be made by human subjects "for the greater common good" is thus subverted and accurately contextualised as being limited by—because it is dependent upon—public confidence and support. This is an exemplary beginning.

After summarising the current regulations in place through guidelines, codes, principles and provisions for minimising risks, the report emphasises that these are merely starting points from which to raise the question of whether human subjects are adequately protected. It cautions us that merely having these in place does not automatically imply that they are adequate or indeed that they are being followed; it is important to periodically re-evaluate guidelines and regulatory frameworks. Thus, while it is necessary to have regulations

in place, they are not necessarily sufficient to completely protect human subjects. The report additionally alerts us to the fact that researchers may be too mired in the pursuit of knowledge to understand all the implications of that pursuit on human subjects. They write, "[a]s subject matter experts may sometimes fail to appreciate all implications of their work, substantive contributions by others, not directly engaged, may provide unexpected and positive contributions" (1: 47).

According to the review, the current US system provides *substantial but not optimal* protection for human subjects from ethical violations. There is significant room for immediate change in several areas to avoid or decrease the possibility of unethical treatment by increasing accountability. They make 14 recommendations which include the following:

1. Improving access to basic information about the scope and volume of human subject research funded by the government, through the establishment of online or other potentially public access systems. This would concomitantly enable research into the ethical and social dimensions of human subject research, which also needs to be supported.
2. Affirming that human subjects should not individually bear the costs of care required to treat harms resulting directly from that research.
3. Requiring the link between regulations and the ethical principles that ground them to be made more explicit so that these are seen as part of the professional make-up of the researcher, rather than as a tedious chore to be followed because of statutory requirements.
4. Amending the "Common Rule" to include the duties and responsibilities of investigators. Currently, the Common Rule focuses on informed consent, independent ethical review and minimisation of avoidable risks but remains silent on the duties of investigators and/or funders towards human subjects.
5. Expanding ethics discourse and education at all levels such that ethics and particularly bioethics becomes an integral part of medical education.
6. Calling on the American federal government to recognise and respect the equivalent protections offered by international partners. This is considered important because though some countries have far better (because more stringent) human subject protection than the US no comprehensive policy has emerged on the American side to interpret and determine this "equivalency".
7. Promoting community engagement as the first step to ensure ethical research.
8. Ensuring ethical study design and justifying site-selection, especially when it is in low income communities in the US as well as abroad.

In the next part of this article, I discuss some aspects which could be of interest in the Indian context.

When detailing regulatory standards for ethical practices, the report at the outset underlines the fact that it is the internal ethical motivation of the investigators which promotes compliance. This may emerge from the internal moral sensibilities of some individuals but it also "can and should be cultivated through education which effectively emphasizes the importance of ethics and a keen sense of social responsibility in professional life" (1:32). Unfortunately, exposure to ethics is not considered worthy of study in the Indian context which focuses on a technical approach to education, with an emphasis on information and regurgitation of facts, rather than analysis, discussion and critique. Ethics thus gets reduced to standards or rules one has to follow, which in turn are "seen as a barrier or a burden rather than as an integral part of the web of respectful human relationships"(1:44). The report points out that while rules are important in ethical research, for a genuine ethical code of conduct to emerge, the principles underlying those rules need also to be understood. As of now, few courses in ethics are offered in India, even as an optional course. These need to be developed and expanded, and include both theoretical ideas as well as case reviews at all levels of education.

The discussion on informed consent illustrates some of the above points. While referring to informed consent forms, it points out that "consent forms may frequently fail to include some of the most important pieces of information that a person would need in order to make an 'enlightened decision' (to quote the *Nuremberg Code*) to enrol in a research study" (1: 99). In my experience, not only do such forms or subject information forms convey information in ways that even an educated person cannot understand, they tend to emphasise the role, indeed responsibility, of the potential *human subject* in advancing science, and de-emphasise the responsibility of the researcher for any side-effects, illness or injury caused by the intervention. Frequently, this responsibility of the researcher or funder is not put in writing, thereby putting the onus on the human subject to battle with the system when there is some wrongdoing. The report is even more categorical about this when it says, "rather than presenting the information in a way that is most helpful to prospective subjects—such as explaining why someone might want to choose not to enrol—the forms often function as sales documents, instead of as genuine aids to good decision-making." (1: 99). This is a remarkably bold and critical statement to make, especially given the power of private funding (and consequently marketing) in the US.

There are two more well-argued sections that are worth noting: one on compensation, the other on reparation and retribution. The section on compensation categorically states that in case of illness or injury arising from participation in the research, medical care must be provided free of cost to the human subject. What is interesting is that this dictum is formulated as the *duty of the researcher/funder* rather than framed to be within the *rights of patients*. Such a formulation, like others through the report, appears to put an unconditional and non-evadable ethical responsibility *on the researcher/funder,* rather than something that arises from a rights discourse in civil society.

We see this clear thinking and position again when two common arguments which are customarily brought up against compensation are examined. The first one is when researchers try to evade the question on compensation by using the argument that their research is always, and only, to benefit the general public (rather than for the specific benefit of the researcher or the funder). But this argument does not hold much water with the Commission. They point out, "[t]he argument instead is that voluntary acceptance of risk by human subjects, which advances the interest of the biomedical research enterprise, warrants benevolent and just responses" (1: 60). Thus, there is a firm and clear assertion that not only the letter but the spirit of compensation must be understood and accepted before it can be followed.

The second argument is made by those who want to project medical research on human subjects as an activity where there is a market-like situation at work, with researchers and human subjects both motivated by private gain and entering into a contract. They may ask: Where's the question of compensation when both are entering of their own free will and there is no coercion? Surprisingly, the report specifically points out that even when the human subject is a "wage-earner," the case for compensation is *actually enhanced* on the principle of justice, rather than diminished. They argue, "If research subjects are employees, and employees in a dangerous job, then how can they be justly excluded from a form of worker's compensation that is available to other employees in other industries? Clearly any harm caused to their health by virtue of their participation in the research would be 'work-related' injuries that ought to entitle them to compensation" (1: 61). This justification is again astonishing coming as it is from the bastion of neoliberalism. It is also germane to the neoliberal Indian context where increasing capitalism has inevitably and inexplicably led to an erosion of the concept of labour as well as labour rights.

The section on restitution and reparation (1: 63) is also of interest. Restitution encompasses the principles of beneficence and malfeasance to justify treatment or compensation for the costs of treatment, thereby achieving distributive justice. Reparation, on the other hand, refers to 'moral repair' (1: 63), or 'making amends for past institutional wrongdoing or that of their former agent' (1: 63). It "calls for acknowledgment of wrongdoing and contrition, along with actual or symbolic repayments for wrong-doing" (1: 63). This distinction shows the kind of gravity of approach and clarity of understanding which has gone into the report. Ethics is not just a matter of right and wrong in accordance with some principles, but pushing these very principles to ensure that grievously felt and experienced harm to human subjects is not just a matter of restitution, but also of acknowledging that something wrong has been done. Obama's apology to the people of Guatemala for wrongdoing committed in the STD trials in 1946-1948 is part of reparation.

The report also points out the need to examine site selection more carefully, both domestically as well as internationally, especially "when the circumstances of selecting research sites suggest the possibility or appearance of exploitation and failure to respect individual human dignity or appropriate community interests" (1: 45). It is unclear how this would play out in international locales but the report suggests that "engaging with the local community prior to beginning research may be one way to show respect and sensitivity to local ethical norms which are also relevant to protect human subjects" (1:45). To my mind, this was the weakest section in the entire document because it seemed to ignore the *realpolitik* of this position. In many developing countries, for instance, an American represents power; as biomedical researchers, they would be perceived to be even more powerful. How then would one expect this hierarchy to be overcome and the relationship made more humane?

The report ends as it began by emphasising the need for accountability, this time even for action on the recommendations: it is incumbent on "entities within the government to respond with changes to the status quo or, if no changes are proposed, reasons for maintaining the status quo with regard to the recommendations" (1:102). Overall, this is a surprisingly bold and well-argued report, deceptive in its simplicity. We would do well to emulate this approach in the generation of ethical norms for human subject protection in India.

Reference

1. Presidential Commission for the Study of Bioethical Issues [Internet]. *Moral Science. Protecting participants in human subjects research*. Washington: 2011 Dec [cited 2012 Feb 21]. Available from: http://bioethics.gov/cms/sites/default/files/Moral%20Science%20-%20Final.pdf