Establishing modern medical research environment based on current international standards

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I have very recently the opportunity to start a research post at University of Colorado school of medicine. My involvement in this new experience allowed me to see how the developed world is approaching research on human subjects. What they have achieved is not an overnight effort. What they have in place is the product of decades of evolution. In their endeavour for research they made mistakes and learned from them. Research on human subjects is multifaceted, yet the corner stone of it is the human being himself. Academics and scholars reviewed all the times when humans were used as research material against their will and without any consideration to their safety. These bad experiences take place on large scales during 2nd world war in Japan and Germany. Upon those grave violations of human right the world came out with Geneva Convention to put the fundamentals of protecting human rights in research. Surprisingly an infamous clinical study took place in USA from 1932-1972. US Public Health Service, working with the Tuskegee Institute, began a study to record the natural history of syphilis in hopes of justifying treatment programs for blacks. It was called the "Tuskegee Study of Untreated Syphilis in the Negro Male." The study was conducted without the benefit of patients' informed consent. Researchers told the men they were being treated for "bad blood," a local term used to describe several ailments, including syphilis, anaemia, and fatigue. In truth, they did not receive the proper treatment needed to cure their illness.[1] Events like these were raised by politicians, human rights activists and academics. They were the drive behind the current robust legislations and regulations involved in any research including human subjects. The result of these abuses was the National Research Act of 1974 and the development of the Belmont Report, which outlined the primary ethical principles in human subjects review;[2] As a result they established an institutional review board (IRB), also known as an independent ethics committee (IEC), ethical review board (ERB), or research ethics board (REB), is a type of committee that applies research ethics by reviewing the methods proposed for research to ensure that they are ethical. Such boards are formally designated to approve (or reject), monitor, and review biomedical and behavioural research involving humans. With the main objective is to assure that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in a research study. Similarly many developing countries have established National, regional or local Institutional Review Boards in order to safeguard ethical conduct of research concerning both national and international norms, regulations or codes.

Nowadays, the US academic and research institutes have local IRBs to approve any research protocol involving human subjects . And the IRB will keep strict and regular follow up measures during the research process to insure adherence to protocol and human subjects safety. Hence, the authority can stop any research violating the approved protocol. IRB is not the only authority working to protect human rights in research environment, there are the Food and Drugs Administration (FDA), department of health and human services; all are the main over arching authorities to empower IRBs and ensure that all researches including human subjects are strictly adherent to regulations protecting the rights and safety of the study subjects. The 1st step in the process is to have the subjects informed consent about participating in the study. This simple document would explain in written form and simple language the research aim, benefit and risk. The subject will be given enough time to read and understand the consent. He should be given the enough

time to ask all what he needs about the study. Most importantly he will be given the right to withdraw his consent any time without giving explanations. His withdrawal shall not affect his rights to have the proper management for his disease. The research does not necessarily need to be interventional in order to obtain an informed consent from the participant. Even observational studies need to provide informed consent. There are specific situations where regulations provided a waiver for consent.

These strict and robust measures are a normal measure in countries where new medical devices and drugs are manufactured. These new products needs to be tested on humans to prove efficacy and to know their down sides. With the fierce economic competition between medical companies, they would violate any human rights to get into the market. Hence, these tough IRB and FDA regulations are in place as a counter measure; the need is the mother of invention.

What about us, where are we from what is happening in the world when it comes to medical research. Do we need to copy these measures and implement them in our medical institutions just to say we are following international standards? Or we should be realistic to adopt what fits our true status. Medical research in Iraq is still in its infancy when we compare it to developed world. We are actually end users of what the modern world produces from devices and medications. We don't have the infrastructure to conduct clinical trials for new drugs and devices. That is the reality, so what kind of IRB we need? How strict our research regulations need to be? Actually, the studies in our medical institutions in majority of them are case reports, case series or cross sectional studies which fall at the bottom of medical evidence pyramid.[3] All such studies are observational or retrospective studies which may not require a written informed consent. What we actually need from the doctors at this stage is authenticity of data claimed in the studies, adherence to basics of research methodology and finally learning how to write properly for publication. We can't jump to higher level of medical research like clinical trials unless we master the earlier steps. Unfortunately we are still having doctors don't know what is plagiarism and many studies lack the basics of research methodology. We don't have a method to authenticate source data when we face exaggerated outcomes.

If we don't admit our flaws we will keep doing same wrong things, if we don't start realistically we will keep having the illusion of we are great then to face the reality of repeated failures.

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