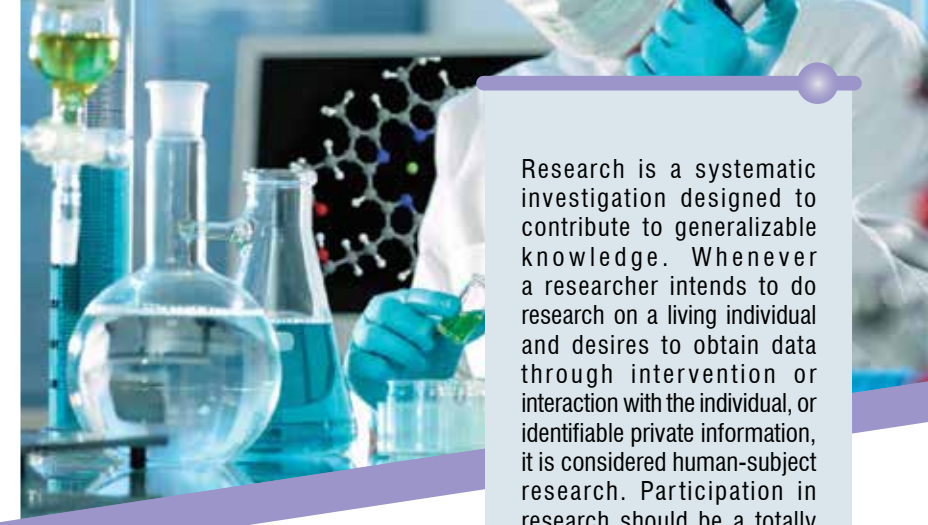
ARTICLES

Institutional Review Boards



By Lama Jamhawi

Research is a tool used to advance science and contribute to new discoveries. It starts with an idea or theory, a written protocol or research plan, and scientists who follow scientific methodologies and multiple steps to prove that the theory is not false. For example, almost all invented drugs that are in use right now have been rigorously tested in a laboratory setting as well as on animals (animal research) before being tested on humans (human research) and used commercially.

Historical background and need

History is full of examples that show times when advancing science took precedence over protecting human subjects. One of the most infamous studies is the Tuskegee Syphilis Study (1932 to 1972). The US Government Public Health Service conducted a study of the natural history of syphilis. Six hundred poor African American men were recruited and told that they were receiving a special treatment, which was actually a diagnostic lumbar puncture physical assessment. They were also coerced into agreeing to autopsies after their death so that their survivors would receive funeral benefits. The autopsies were done at local hospitals, and Tuskegee University faculty/staff were involved in the study as well. Although penicillin treatment for syphilis became available in 1947, subjects were neither provided with it nor given information about it.

This incident and many others triggered the establishment of national committees and court trials that formed the basis for current international regulations for the protection of human subjects in research. There was a clear need to have an impartial body to review research projects conducted on humans before and during the projects in order to protect the rights of human subjects as well as ensure their safety and well-being. These bodies are called institutional review boards (IRBs) or research ethics committees (RECs).

> Research is a systematic investigation designed to contribute to generalizable knowledge. Whenever a researcher intends to do research on a living individual and desires to obtain data through intervention or interaction with the individual, or identifiable private information, it is considered human-subject research. Participation in research should be a totally voluntary action. Who makes sure that participants are fully informed about the research and about alternatives, if any? Who ensures that they are aware of potential risks and anticipated benefits? Who ensures the safety and well-being of participants as well as confidentiality?

IRB composition and function

IRBs are formally composed committees of at least five members of various professions, specialties, and backgrounds. Committees must include both men and women, and there must be at least one member who is primarily a non-scientist. This membership variety is needed to ensure a comprehensive review that takes into consideration various viewpoints.

Any study that proposes to conduct human-subject research must submit the research protocol and all study-related materials to the IRB for review. No human-subject research can be started prior to receiving IRB approval.

The IRB is trusted to review the research protocol and all study-related material. In addition to approving or rejecting any project, the IRB can require specific modifications as a condition for approval.

IRBs are managed by an IRB manager or administrator, who provides guidance to researchers, IRB staff, and members regarding the interpretation of regulations, laws, and policies. IRB staff coordinate IRB meetings, ensuring that members receive the research plan and all related materials (consent documents, questionnaires, advertisements) in advance of the meeting in order to allow adequate preparation for the meetings.

Key ethical principles

In the IRB review three main ethical principles are taken into consideration as outlined in the Belmont report[1]: beneficence (maximise benefits and minimise risk), respect for persons (offer information and respect choices), and justice (distribute benefits and risks, not taking advantage of vulnerability).

Criteria for approval

The following criteria are essential for IRB approval of a research project: minimisation of risks; reasonableness of risks relative to benefits and the importance of the knowledge to be gained; equitable selection of subjects; informed consent; adequate data monitoring to ensure safety; privacy protections; confidentiality measures; safeguards for vulnerable subjects.

Special populations

Some human-subject research populations are more vulnerable than others and need extra protection to ensure their safety and well-being, such as adults unable to consent, children, pregnant women, and prisoners. Inclusion of any of these populations triggers a certain set of regulations.

Research in Palestine

Many national and international research projects take place in Palestine. For an IRB to approve any project, risks and benefits must be assessed, and equitable distribution of benefits (if any are anticipated) among participants from all sites must be ensured.

One recent project,[ii] which was conducted by researchers at Kingston University in the United Kingdom, the University of Tampere in Finland, and the Islamic University of Gaza, was funded by the Qatar National Research Fund and reviewed by the Joint Institutional Review Board (JIRB).[iii] According to the researcher Dr. Muthanna Samara, "Traumatic events can make a devastating impact on someone's health and life, threatening their sense of security for years to come. This could lead to the development of Post Traumatic Stress Disorder (PTSD). Children in Palestine are one example of this exposure to traumatic events on a daily basis, which negatively affects the entire region of the Middle East. The study is a unique opportunity to follow a large sample of children who have been exposed to continuous war trauma in Gaza compared to children exposed to traumatic experiences in Qatar due to accidents, illnesses, injuries, abuse, and neglect, experiencing or witnessing violence, physical and sexual abuse, and paediatric intensive care admission. The aim of the study is to make recommendations to appropriate bodies and design a suitable intervention program to help these children, especially after the recent aggressive war against the people in the Gaza Strip."

Science and research ethics should go hand in hand; the advancement of science should never take precedence over the protection of human subjects in research, which is everyone's responsibility – IRBs, researchers, human subjects volunteering in research, and the community as a whole.

Lama Jamhawi is a certified GCP and IRB professional with an MSc in immunology and allergy from the University of Nottingham in the United Kingdom and a BSc in biological sciences from the University of Jordan. During the past ten years, she has been involved in establishing multiple Human Subjects Protection initiatives and ethical review boards.

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[i] Full title: Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 1979.

[ii] "Continuous Trauma and PTSD in Qatar and in the Gaza Strip: Risk Factors and Causes, Consequences and Resiliency Factors," Dr. Muthanna Samara, Kingston University; Dr. Mahmoud Elsaid, HMC; Professor Samir Qouta, Islamic University of Gaza; Professor Raija-Leena Punamäki, Universtiy of Tampere, July 2014.

[iii] JIRB is the reviewing board for Hamad Medical Corporation (HMC) and Weill Cornell Medical College in Qatar (WCMC-Q).