

Archives of Surgical Research | Invited Commentary

"Rules of Thumb" for Research Ethics

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IMPORTANCE Research ethics provide guidelines for responsible conduct of research and educate and monitor scientists', conducting research to ensure a high ethical standard. Research ethics are significantly important for a number of reasons. They promote the aims of research, such as expanding knowledge and support the values required for collaborative work like mutual respect and equity. These pillars make a foundation of important social, moral values, and the principle of doing no harm to others. Ethics in research are associated with the ethical principles of social responsibility. Usually, research envelops a vast framework of working with people and researchers put up with this endeavor to gain trust in the respondents' eyes, to be able to collect authentic reliable data, and also to ensure the transparency of the scientific work.

KEYWORDS Research Ethics, Beneficence, Informed Consent, Patient Safety

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Research ethics provides ground rules to researchers on how to conduct research in an effective manner while maintaining high ethical standard. These ethical principles matter a great deal for a number of reasons like enhancing knowledge and cultivating mutual regard and integrity for collaborative work among the researchers. These pillars make a foundation of significant moral and societal standards, and the principle of preventing harm to others and are associated with the ethical principles of social responsibility. Usually, research envelops a vast framework of working with people. Researchers put up with this endeavor to achieve trust in the respondents' eyes, to be able to collect authentic reliable data, and also to ensure the transparency of the scientific work.

There are a few principles in ethics that should be followed while conducting a research study. The word autonomy has been originated from ancient Greek, meaning 'self-legislation' or 'self-governance. In other words, it is the individual's capacity to act in accordance with their own values and interests. It is based on respect for individual and value of person as an end in itself thus enabling or empowering patients to make their own decisions about their health care interventions. In order to treat an individual as autonomous, he must be provided with complete information about the research project and given a choice to participate or refuse. The participants of research study should be informed about their right to decline the intervention at any point of time during the ongoing research. It has been observed that it is the highly overlooked ethical concern while conducting a research.

Individuals with diminished autonomy and mental proficiency, psychosocial stressors and developmental disabilities are the vulnerable populations who should not be excluded from research, as if done so, it will restrict knowledge development in those domains where these population may get benefitted by an authentic research work. Under special circumstances, the consent can be obtained from family, legal guardian, or a custodian.

Beneficence is balancing the gains of treatment in opposition to the expenditure and risks associated with that particular mode of therapy, whereas non-maleficence means avoiding the causation of harm. For example, it may be an essential treatment but is not considered to prevent a more serious health issue in future. The purpose of research is to help the society by exploring contemporary and safer treatment modalities. To some extent, participants may get exposed to discomfort, harms, and risks during the research process and it is the responsibility and moral duty of investigator to reduce the harm and augment the welfare. Research integrity refers to active observance of ethical principles and professional norms that are essential for effective research practice. It does not mean taking it as a directive by law makers but following it as a part of personal belief system. The integral component of research process is integrity because it builds up trust and confidence. The individuals involved in research should respect and acknowledge each other's work, and "they must also be trusted by society since they provide scientific expertise that may impact people's lives". Confidentiality is an ethical practice used to build up trust and rapport with the

participants involved in the study by protecting their privacy thus maintaining the moral standards and dignity of research process. Protecting and respecting patient confidentiality is mandatory to build a relationship on the basis of trust and respect.

Informed Consent is a voluntary agreement to participate in research and this choice is based on the fundamental principle of altruism i.e., to benefit others in society. It can be on the expense of potential disclosure of their personal information, so it is the duty of researcher to protect the participants. It is not merely a form that is signed but is an important procedure, in which the subject is provided with adequate knowledge about the research, making sure that he/she understands the benefit to risk ratio, that helps in making an informed, voluntary, and rational decision to participate. This also includes information on their right to decline or withdraw.

Ensuring justice in research commences with selecting subjects based on research requirements rather than expediency. Inclusion and exclusion criteria should be explicitly mentioned in the study design and followed so that every participant can have an equal opportunity to

participate in the research. It is the ideal distribution of risks and benefits when scientists are recruiting volunteers, to participate in clinical trials. In randomized trials, the investigator is in charge to establish an independent group of experts in a Data and safety monitoring board to monitor the level of risks associated with experimental treatment and study procedures, in order to ensure the safety of participants. Conflicts of interest implies those situations when professional decisions related to a major interest (e.g., the responsibilities of a medical researcher) may be at risk of being shadowed by a subsequent interest (e.g., monetary benefit or career growth). The investigators can achieve mitigation of conflict of interest, by complying with the institutional and governmental regulations, adhering to the prerequisites for recognizing, disclosing, and managing conflicts of interest, and circumventing and minimizing conflict.

Research ethics are comprehensive from developing to usage and applying knowledge. It is the primary obligation of investigators to devise safe strategies for all participants to take part in the research process in a fully informed and ethical way despite their literacy level or physical or intellectual capacity.

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