Principles of Ethics in Medical Research

The 12 general principles of ethics in medical research as described in the "Indian Council of Medical Research. Ethical Guidelines for Biomedical Research on Human Subjects 2006" guidelines are as below. These are common to all areas of biomedical research.

1. **Principles of essentiality:** Whether the research is considered to be absolutely essential after a due consideration of the existing knowledge in the proposed area of research. The proposed research should be carefully examined by an independent and responsible body of persons who, after careful consideration, come to the conclusion that the said research is necessary for the advancement of knowledge and for the benefit of mankind and environment.
2. **Principles of voluntariness, informed consent and community agreement:** The participants are to be informed about the research and the impact and risk of the research on them and others. They should be informed about their right to abstain from further participation in the research irrespective of any legal or other obligation that either they may have been entered into or by someone on their behalf, subject to only minimal restitutive obligations of any advance consideration received and outstanding.
3. **Principles of non-exploitation:** All research participants are remunerated for their involvement in the research or experiment. They should be kept fully apprised of all the dangers arising in and out of the research, irrespective of their social and economic condition or status, or literacy or educational levels, so that they can understand all the physical and psychological risks including the moral implications of the research whether to themselves or others, including future generations.

   Each research shall include an in-built mechanism for compensation for the human participants either through insurance cover or any other appropriate means to cover all foreseeable and unforeseeable risks by providing for remedial action and comprehensive aftercare, including treatment during and after the research or experiment.
4. **Principles of privacy and confidentiality:** The identity and records of the human participants of the research or experiment are to be kept confidential as far as possible. No details about the identity of human participants are to be disclosed without valid scientific and legal reasons without the specific consent, in writing, of either the human participant concerned, or someone authorized on their behalf. It should be ensured that the participant has come to no harm, or does not face any discrimination or stigmatization as a consequence of having participated in the research or experiment.
5. **Principles of precaution and risk minimization:** All precautions should be taken at all stages of the research so that the study participant and those affected by it including the community are put to the minimum risk, suffer from no known irreversible adverse effects and generally, benefit from the research or experiment.
6. **Principles of professional competence:** The research is conducted at all times by competent and qualified persons who act with total integrity and impartiality. They should be aware of, and are mindful of, preferably through training, the ethical considerations to be borne in mind in respect of such research or experiment.
7. **Principles of accountability and transparency:** The research is to be conducted in a fair, honest, impartial and transparent manner after full disclosure is made by those associated with the research or experiment of each aspect of their interest in the research. Any conflict of interest should be disclosed. All records pertaining to the research including data and notes should be retained for the prescribed time period or as required by the law, or for conducting further research such as post research monitoring.
8. **Principles of the maximization of the public interest and of distributive justice:** The research and its subsequent applicative use are conducted and used to benefit all human kind and not just those who are socially better off but also the least advantaged; and in particular, the research participants themselves and or the community from which they are drawn.
9. **Principles of institutional arrangements:** All persons connected with the research have the duty to ensure that all the required procedures are

complied with and all institutional arrangements required to be made in respect of the research and its subsequent use or application are duly made in a bonafide and transparent manner. All research reports, materials and data connected with the research are to be duly preserved and archived.

10. **Principles of public domain:** The findings of the research should be brought into the public domain so that its results are generally made known through scientific and other publications subject to such rights as are available to the researcher and those associated with the research under the law in force at that time.
11. **Principles of totality of responsibility:** All those directly or indirectly connected with the research or experiment including the researchers, those responsible for funding or contributing to research funding, the institution/s or where the research is conducted and the various persons, groups or undertakings who sponsor, use or derive benefit from the research, market the product (if any) or prescribe its use are entrusted with the professional and moral responsibility, for the due observance of all the principles, guidelines or prescriptions laid down generally or in respect of the research or experiment in question.
12. **Principles of compliance:** There is a general and positive duty on all persons, conducting, associated or connected with any research entailing the use of a human participant to ensure that both the letter and the spirit of these guidelines, as well as any other norms, directions and guidelines which have been specifically laid down or prescribed and which are applicable for that area of research or experimentation, are scrupulously observed and duly complied with.

■■■■

Neighborhood Characteristics Independently Impact COVID-19 Hospitalizations: Study

A study published in *PLoS ONE* suggested that the built environment of neighborhoods plays an independent role in determining the risk of individuals being hospitalized due to coronavirus disease 2019 (COVID-19).

The study examined neighborhood characteristics in the Denver Metro Area and their association with hospitalizations among 18,042 people who tested positive for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) between May and December 2020, before the widespread availability of vaccines.

The study findings showed that neighborhoods with higher public transit quality and accessibility were associated with a higher incidence rate of hospitalization. The study also identified differences between the two largest ethnic groups in the region. Latinx individuals had a higher hospitalization rate in areas with higher PM2.5 levels, while density and overcrowding showed stronger associations for non-Hispanic White individuals.

After accounting for biological factors, the study identified four neighborhood characteristics that contributed to COVID-19 hospitalizations, namely density and overcrowding, environmental hazards (such as air pollution and proximity to highways), environmental amenities (including access to parks), and mobility options (such as public transit, walkability and bike-ability).

The authors were not surprised by the finding that individuals with compromised lung and immune systems exposed to chronic air pollution would have a higher risk of severe disease and hospitalization after contracting COVID-19.

Furthermore, the study highlighted the disproportionate impact of air pollution on People of Color, as higher PM2.5 levels affected Latinx individuals more than non-Hispanic White individuals. (*Source: https://www.news-medical.net/news/20230714/Neighborhood-environment-can-increase-risk-of-COVID-19-hospitalization-study-reveals.aspx*)