

Ethical Research during Public Health Emergencies

Bidita Khandelwal*

Associate Dean-Research, Professor & ex HOD Medicine, Sikkim Manipal University, India

***Corresponding author:** Bidita Khandelwal, Associate Dean-Research, Professor & ex HOD Medicine, Sikkim Manipal University, India.

Citation: Khandelwal B. (2020) Ethical Research during Public Health Emergencies. *Adv Clin Med Res.* 1(1)-1-4.

Received: May 18, 2020 | **Published:** June 02, 2020

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Keywords

COVID 19; Public health emergencies; Ethical research

Introduction

The World Health Organization declared the COVID-19 outbreak a pandemic on 11 March 2020. The situation is evolving rapidly with cases and deaths increasing with each passing day. It is necessary to conduct research during public health emergencies and humanitarian crisis as problems related to it can be adequately investigated only then. The effectiveness of health response to those effected by such emergency, can be enhanced if research is conducted ethically in the prevailing complex and challenging environment.

WHO guidelines for Ethical Standards for research during public health emergencies, Global Research Collaboration for Infectious Disease Preparedness Research Roadmap for COVID 19, Guideline 20 of the updated International Ethics guidelines for Health related Research Involving Humans (2016) by the Council for International Organisations of Medical Sciences (CIOMS) and National Guidelines for Ethics Committees reviewing Biomedical & Health Research during COVID 19 by Indian Council of Medical Research provides guidelines regarding research during such situations with the aim to generate knowledge quickly, expedited approval for conducting and implementing such research and simultaneously adhering to all principles of Ethical research.

Any activity which generates data with the primary aim to improve the health related aspects of emergency response is considered as research. All research, whether it is operational or formal

academic, needs to be carried out ethically. Often there is a debate between ethics in practice and in procedural ethics. The 2016 CIOMS International Ethical guidelines supports the point that critically ill patients have moral right to try unvalidated medical interventions (UMI) and thus restricting clinical trials on UMI is in fact unethical. Another important aspect is that there is no equipoise between a standard of care that offers minimal benefit in a high mortality disease and an UMI which might actually be superior.

Research should not impede emergency response efforts. Research is an important response to public health emergencies but at the same time it should not take away the resources (personnel, equipment, facilities etc.) from that required for the outbreak management. Routine health care and public health services should not be hampered due to research.

Collaborations and Partnership

Persons with different types of expertise coming together to work coherently results in meaningful effective research. Funders should ensure research teams to collaborate as numerous agencies which need to work together for a meaningful research may have conflicting priorities. In order to avoid duplication and wastage of resources, there should be good coordination between national and international agencies in conduct of research and in rapid sharing of information generated so that it can be effective in tackling the emergency. Council on Health Research for Development (COHRED) guidelines should be adhered to for fair research collaborations.

Community Engagement

Local priorities should be kept in mind and the research should benefit the participating community during the present crisis as well as prepare them better to tackle similar crisis in future. Involving researchers from local context at all feasible stages of research can make the research more responsive and sensitive. Giving importance to local beliefs, values, needs and culture helps to build trust and lasting relationship with the participants. Community engagement in an inclusive manner involving all those are concerned (including the marginalised and vulnerable) should be ensured. Insight into the experiences of affected persons is an essential pre requisite of a research as in any humanitarian crisis, research and response are closely related. The basic needs of the participants should be met before expecting them to trust a researcher. Educating the community about the pandemic along with the proposed research, the researcher should also prevent the spread of fake news and fake claims.

Lack or absence of local expertise and resource for ethics review should not hamper research. Independent Ethics Committee can assist in research involving human participants. Routine public health activities, not constituting research can be carried out keeping in mind WHO guidelines on Ethical Issues in Public Health Surveillance. Expedited review to facilitate research can be done without compromising human participant's protection. Full ethical review can follow whenever possible.

Adaptation of Methodology

Without compromising the scientific validity and social value, is permitted in research conducted during public health emergencies. The research design should be appropriate to address the research question

and resulting in valid and reliable answers which would help in the management of the emergency. Is this the right study for this locations and this population is a vital question which should be answered before adopting a population / subpopulation as well as excluding any. Social distancing norms may be a barrier to conventional method of data collection. Technological requirements maybe there in the study and the participants should have access to it in order to be eligible.

The general principle of respect for all should be always be followed during selection of participants. One should ensure minimal risk, include vulnerable populations with reasonable justification, and maximize social value and collaborations. A fundamental ethical requirement for any research is an individual informed consent. Uncertain risks and the perception that any intervention is better than no intervention could influence the participant's decision. The ethics committee should ensure that reasonable scientific care has been taken which indicates that the intervention may be safe and efficacious with minimal risk to the participants. Consent is a part of the wider "ethics ecosystem" and it alone is not sufficient. In unavoidable circumstances when informed consent is challenging, research can still be permitted with other aspects of ethics being strengthened. Novel methods of obtaining recording consent, considering the cultural and linguistic differences in a community and incorporating them help to build trust.

Sharing of research data and samples

Research participants and stakeholders are to be well informed regarding the collection, storage, future use, bio banking and export of human biological material. Institutes which have substantial sample should share this information to be kept at a combined platform from where it is accessible for future use without being exploitative. Centre for Disease Control or WHO can be custodian of all such samples as a bio repository and have an open access database, whatever is permissible, within the ethical guidelines. Prompt sharing of information to the persons involved in response efforts should be followed by sharing to the affected population, the participating subjects and the global community. The information should be shared before journal publications and journals should not exempt from publications due to preprints.

Funding and Funding Agencies

Limited resources and short time frames are practical challenges of coordinating funding. Thus, a dedicated source of funding at all levels, government, private organisations or individual, needs to be coordinated. The funding agencies should not only effectively promote and support collaborations using creative means; they should also provide opportunities for partnership between high income countries and low and medium income countries. National government should prioritize capacity building and support development of expertise by ensuring that the National Ethics body is well resourced. The Institutes should ensure that researchers who are in collaborations are appreciated and supported for it but at the same time do not neglect their assigned duties.

Sharing of Research Benefits

Any benefit that results from research should be shared with the participants as well as the community. It is the duty of the researcher as well as the funding agency to provide the beneficial effect of research

to the participants. The participants, who in time of real crisis and distress, consent to be part of research and thus contribute to a greater cause, needs to know the benefits and be acknowledged.

There are three categories of research during a pandemic. New research directly related to the pandemic, ongoing research unrelated to the pandemic and new research unrelated to pandemic. New non COVID research should not suffer during a pandemic. EC has additional responsibility to see if any such research has negative impact or increased risk to participants due to the pandemic.

Today we are flooded with research pertaining to COVID 19. It is essential to take research on a priority basis in order to tackle the novel challenges which have been posed to mankind in an unprecedented manner. Research during such pandemic warrants the need for novel methodologies, innovative design, technological applications etc and all this within the constraints of time and available resources. The responsibility of the research community is of paramount importance to ensure that the research is conducted ethically and communicated promptly.

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