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AN ANALYTICAL ARTICLE ON A PROPOSED ROADMAP FOR ETHICS IN BIOMEDICAL AND HEALTH RESEARCH DURING THE DAYS OF GLOBAL PANDEMIC OF COVID-19

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KEYWORDS :

We all are aware of the facts that the global healthcare community is writing pages in history everyday while fighting the humanitarian, medical, psycho-socio-economical pandemic of COVID-19, the most critical threat to our current human civilization.

Research is very much necessary to ensure appropriate, effective provisions to combat in a manner that reduces mortality and morbidity, but, there lies a confrontation between two hands, one holding the vital necessity of fastening research on priority basis and on the other hand, lies the valuable question of uncompromised integrity and ethical review of the process managing through practical field obstacles in present situation of lockdown and prevailing requirement of social distancing with minimal exposure.

Now, to that this tackle this crucial issue and " to guide quality research outcomes in a time bound manner", confirming fast track process with robust in ethics review as well as monitoring participants' safety and rights at all times; managing the challenges impacting socio-behavioural wellbeing and also ensuring continuation of non-COVID researches, ICMR (Indian Council of Medical Research) bio-ethics unit has developed an unique "NATIONAL GUIDELINES FOR ETHICS COMMITTEES REVIEWING BY MEDICAL AND HEALTH RESEARCH DURING COVID-19 PANDEMIC".

As the pandemic has hit the nation hard, India is fighting harder with 67,138 reported cases, 2,212 deaths as per the latest statistical updates on the 10th of May 2020. The story worldwide is really gloomy.

In this outset, following strict lockdown protocols, social distancing norms, functioning of research and that of Ethics Committee has become really very difficult, physically - even valid informed consent collection is also a major problem, not only because of practical problems to reach out the patients, but also due to

- the questionable decisional capacity of the hospitalized COVID-19 patient with moderate to critical stage of the disease,
- inability of confused patients to differentiate between relief offered and research components,
- panic looming large among the patients to expose themselves and to any new drug, vaccine or treatment protocol and thus compromising voluntariness and
- phobia regarding social stigmatization, if the confidentiality is compromised.

Apart from that, continuous review and monitoring of research which is an essential function of ethics committee is very cumbersome to achieve.

Not only this much, availability of Ethics Committee members is also a great challenge.

Hence, a proper guideline with approach to all the issues had to be framed. The World health organisation (WHO) has initiated a module with a very brief outline in "Ethical Standards for research during public health emergencies: Distilling existing guidance to support COVID-19 R & D".

Now, ICMR has come out with an elaborative, practical based approach in a tailored and all encompassing fashion, with the first national guideline, rendering necessary esteem to the valid skeletal structure suggested by WHO.

As this comes from a body like ICMR and deals with world's second largest population in India with multiple social and geographical varieties, it holds considerable significance from all points of views. Let us highlight some important and interesting points and measures mentioned here:

1. Risk-benefit assessment should dictate type of review required (Exempted/ Expedited/ Full committee).

2. Information related to COVID-19 is very sensitive being capable of fetching stigmatization, discrimination, violence etc. Hence, PRIVACY CONFIDENTIALITY is pivotal.

3. Distributive justice must be served equally without leading to social, racial or ethnic inequalities.

4. Community engagement in a culturally sensitive manner should be promoted to improve public trust, help improve design, conduct and responsiveness to health needs.

5. Community education about the pandemic, proposed research and involvement of community representatives (eg. Community advisory board) should be undertaken.

6. Prevention of infodemic and dedicated, sincere role of media have been advocated.

7. Post research access and benefit sharing to & with community relevant is advised.

8. Storage of bio-medical samples require adequate safeguard.

9. Confidentiality of individual data and requirement of presenting information at public front should be well balanced.

10. Virus isolation in cell culture and initial characterization of infectious particles recovered in cultures of SARS-COV2

specimens should only be conducted in biosafety level 3 or 4 (BSL – 3 or 4) laboratories with NABL accreditation, following requirements prescribed by Department of Biotechnology(DBT) and Ministry of Environment and Forest, Government of India, strictly.

11. In this present fragile environment, agencies / sponsors / institutions need to ensure appropriate safety funds, care, compensation, including insurance coverage as well as training at individual society and / or community levels for patients, healthcare workers and others engaged in COVID-19 research.

12. Use of technology:

a. For informed consent , electronic consent can be allowed, where "digital signature" needs review and approval of EC.

b. The research proposal which is instructed to be submitted in the ICMR forum for ethics review can be submitted in soft copy and electronic documents can be accepted for review and timelines to be shortened for accelerated procedure.

c. Suitable virtual software platform with facilities of video and teleconference has been highly advocated.

d. Telemedicine can be used for research when possible.

e. Ethics committee meetings, proposal submission to National Secretariat, review of research, follow up with participants should be maintained with minimal physical interactions and carried out via text, graphics, audio, video, podcasts, interactive websites etc. Audio and video recording can be done as a process of documentation with prior intimation.

13. Ethics Committee: Should be discrete, acting in fast track, with predetermined short lined agenda, increased frequency of meetings virtual in nature and preferably reviewing within 24-48 hours.

14. To fasten the procedure, EC may collect expert opinion by clarification from the researchers before the meeting and even invite non-voting special invitee who is supposed to leave the meeting before coming to the conclusive decision of the EC.

15. Vulnerability : COVID-19 patients and also healthcare workers in COVID-19 hospitals including doctors, nurses, ward staff, sanitation workers, security personnel, food suppliers, other socially, economically or politically disadvantaged individuals such as stranded migrant workers who are susceptible to be exploited are all vulnerable persons.

16. Autonomy and voluntariness are to be upheld with priority.

17. Safety psychological health and social wellbeing of the COVID-19 patients, patients in isolation, family members of all the patients and very importantly of all the healthcare service providers of all categories in wheel, must be taken care of with utmost priority and empathy.

18. Appropriate bio-safety precaution and adequate training and insurance coverage must be ensured for all the healthcare service providers.

19. Ethics Committee must prioritize COVID researches as urgent and at the same time, should come out with decision regarding non-COVID researches with necessary consideration with the intention of not allowing non-COVID researches to suffer due to "COVIDISATION".

The unique guideline has embraced necessary socio-psycho-politico-economical and practical considerations and gifts of developed technology blend in such a perfect blend that the application of the same with necessary modifications of ethical guidelines keeping the core intact will hopefully usher a novel platform for all the stakeholders in medical research such as researchers, sponsors/ regulators/ participants/ publishers and media and society at large in a useful manner in India and probably many other parts of the world to adopt the same with or without necessary audits and edits.

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