Informed consent during Covid-19

We intend to bring the attention of readers to ethical issues for researchers working on Covid-19-related projects. According to the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants by the Indian Council of Medical Research (ICMR) 2017, an informed consent is a prerequisite before initiating any research on human subjects. The consent is considered as complete, valid and meaningful when it satisfies all four criteria of information disclosure, competence, comprehension and voluntariness.

The consent can also be waived by an ethics committee (EC) in certain situations when research involves less than minimal risk, retrospective studies, public domain data, humanitarian emergencies and disasters, public health studies, surveillance, programme evaluation studies and situations where research cannot be possibly carried out without waiving consent.[1]

The National Health Service has accepted a 'Joint Statement on Seeking Consent by Electronic Methods' in 2018 with a primary focus on clinical trials. It discussed electronic signatures as 'simple', 'advanced' or 'qualified' depending upon the true identification of person who signed, time of signature, no alteration in signature and justification through demonstration if required. A simple electronic signature (eSignature) has been advocated to be used for trials with less than minimal risk (type A trial). Some examples of eSignature are tick box declaration, electronic representation of handwritten sign, cryptographic sign, digital representation with fingerprint or retina scan, etc. Phase I clinical trial (types B and C) entails a simple eSignature with tracing properties. However, such a sign should not possess any threat to integrity of research. eSignature with participant tracing is used when participant identification is already disclosed, recruiter is familiar with the participant, and the person seeking consent and treating is the same. However, it has discouraged the use of typewritten or scanned image of handwritten sign. An 'advanced' or 'qualified' sign is used in remote research to facilitate participant verification. These signs identify the signatories, permit them to retain control and detect any changes made in the data.[2]

The 'National Guidelines for Ethics Committees Reviewing Biomedical and Health Research during Covid-19 Pandemic'[3] by ICMR 2020 was an adjunct to the ICMR 2017 ethical guidelines. Conventionally, face-to-face interview and meetings were considered as gold standard to obtain informed consent. However, the new upgradation advocated social distancing and adapting online and remote methods. It is hence essential that technology should be used through text, graphics, audio, video, podcasts, mobile applications and interactive websites. The chosen online procedure should give complete right to the participant to ask questions and clear doubts in the consent process. Video conferencing, telemedicine and electronic consent forms with electronic signatures have been encouraged with incorporation of essential elements in consent such as comprehension, autonomy and competence.[3]

The WHO has also described 'Ethical standards for research during public health emergencies: Distilling existing guidance to support Covid-19 R&D' through nine key points. It highlights the requirements for informed consent in emergencies with emphasis on accepting research interventions after weighing the risk–benefit ratio where minimal risk and greater benefits exist. It further elucidated the need of proper communication with local communities and discussing the circumstances for information sharing.[4]

Consent during the present times

The newer technologies and electronic methods are a boon for the conduct of research in these difficult times. They are easy to handle and store, consume less time, require less paperwork, save funds, decrease dependency on transportation, allow flexibility and are convenient for participants. The choice of electronic signature should be based on the complexity of research, impact upon society in terms of risks and benefits and ethical issues at stake. Extended discussions between the investigator's team and participants should be encouraged by using telecommunication, video-chats, voice or written messages, email, etc. Interactive questioning among participants can be initiated to aid in understanding and boosting their confidence in research. Cross-questioning with yes/no, agree/disagree or teach-back method should be used where participants are requested to describe back the consent form in their own words.

The internet security for each of these media must be evaluated. In order to verify the participants and maintain authenticity in research, an audio or video recording can be used. An audio or video recording stating 'this video is an in-person verification for research entitled with name, date of birth and any identity proof number' can be recorded with signed electronic consent to ensure the originality of the participant. The participants can attach any valid identity proof along with these records for cross-checking. The attendees of online meetings in the consent process can also be recorded. The researchers can use a mobile or laptop specifically for research purposes. A security code can be assigned to the signed consent form, linked with email or mobile number of both participant and researcher to maintain transparency. Hence, both will receive the information whenever the consent is accessed by anyone. An advanced or quality sign can be encouraged such as the UK guidelines, along with GPS and IPS address numbers for possibility of cyber-tracking for security reasons.

Conclusion

Informed consent is a prerequisite for initiating a research project. A smart use of technology through electronic signature, in-person verification and GPS/ IPS address tracking can improve and take the research process to new heights.

Conflicts of interest. None declared

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Shubhi Goel
Nitesh Tewari
Vijay Prakash Mathur
Department of Pedodontics and Preventive Dentistry
Centre for Dental Education and Research
All India Institute of Medical Sciences
New Delhi, India
dr.nitesht@gmail.com