COVD-19

How Can Research Transparency Be Promoted? Actions for National Health Authorities During the COVID-19 Pandemic

Transparency is a central component of the ethical governance of research. In the context of COVID-19, transparency is key to promote public trust in research and in the response to the pandemic. If society and all stakeholders know which research studies are taking place, and the existing mechanisms to ensure studies are conducted ethically, they will be more willing to contribute to research efforts and to trust in the results of research. Therefore, the Pan American Health Organization (PAHO) recommends relevant national health authorities take action to strengthen the transparency of research during the pandemic. The following measures to strengthen research transparency can be implemented immediately; relevant authorities can request PAHO's support for their implementation.

- 1. Require the registration of clinical trials in a registry that feeds the World Health Organization's (WHO) <u>International Clinical Trials Registry Platform</u>.
 - The requirement should apply to all clinical trials (not only those on medicines and medical devices), in addition to any similar requirement that may already exist. The inclusion of all clinical trials in ICTRP ensures that the information about each trial is public and that trials are identifiable with one single search at a global site. Countries do not need to have their own WHO-accredited registry to ensure all the trials taking place in the country show in ICTRP. It suffices to require (e.g. through a ministerial resolution) the inclusion of trials in a registry that feeds ICTRP and that allows for the registration of clinical trials from other countries.
 - Ethics committees and regulatory authorities supervising clinical trials should require investigators to provide the registry information of the trial before enrolling the first participant and to include it in the informed consent documents of the study.
- 2. Make available to the public a list with the basic information of all studies with human participants that have been approved to take place in the country.
 - The website of the relevant health authority should include the list of all studies with human subjects that are taking place in the country. While this is advisable in general, it is reasonable to prioritize the studies with human participants that are related to COVID-19. For clinical trials, the website should include the information of their registration in ICTRP, so it is possible to easily access additional details about trials. Ethics review committees can be required to provide the list at stake to their supervising authority periodically in order to populate this site and keep the information current.



- 3. Inform society about how research is conducted and the mechanisms in place to ensure it is ethical.
 - Relevant national authorities should use their different communication channels (social media, websites, announcements in public spaces, etc.) to inform the general public about the importance of conducting research to find safe and efficacious treatments and vaccines for COVID-19, the manner in which research is conducted, and the safeguards established to ensure the protection and ethical treatment of research participants. PAHO-developed communication resources can be used for this purpose, and authorities can adapt them.
- 4. Require that COVID-19 studies include a community engagement plan as established by international ethical standards.
 - Ethics committees and authorities tasked with the supervision of clinical trials should work in a coordinated matter to ensure that researchers and sponsors conduct community engagement following a plan previously approved by committees and authorities. Community engagement should start as soon as possible and use strategies that are adequate in the context of the pandemic, such as social media and virtual communications. Community engagement should be sought throughout the study. Research teams should thus make available to the public, in a transparent and continuous way, the updated information about the trial through a website.

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