



National Institute of
Allergy and
Infectious Diseases

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ANVISA and CONEP Issue Updated Requirements Related to COVID-19 and Clinical Trials

On April 22, 2020, Brazil's National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária (ANVISA)) issued an [updated technical note](#) providing guidance to sponsors, centers, and researchers related to clinical research and COVID-19. The note provides additional information related to remote monitoring of clinical trials and includes new sections on clinical trials for drugs and medical devices to treat COVID-19. ([Google translation of technical note](#))

On April 14, 2020, the National Research Ethics Commission (Comissão Nacional de Ética em Pesquisa (CONEP)) issued an updated [communication](#) that outlines which COVID-19 related research protocols should be reviewed by ethics committees and which should be forwarded to CONEP for expedited review. In particular, the following types of research protocols should be sent to CONEP:

- Clinical trials
- Protocols in special thematic areas
- Protocols specified by the Ministry of Health, by the health secretaries of the States, Municipalities and the Federal District
- Protocols related to mental health
- Other protocols at the discretion of the ethics committee

([Google translation of requirement](#))