

Rapid Regulatory Frame Work for COVID -19

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Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2), commonly known as 2019 novel coronavirus was first reported from Wuhan, China in December 2019. The impact of the resulting disease, COVID-19, was enormous and by January 2020, the World Health Organization had declared it as a public health emergency of international concern (PHEIC). Deeply concerned both by the alarming levels of spread and severity, WHO declared it as a pandemic in March 2020.

The [Department of Biotechnology](#) (DBT), Ministry of Science & Technology has been proactively working on the development of Diagnostics, Therapeutics, Drugs and Vaccines to combat the healthcare challenges posed by COVID-19. DBT has also taken several measures to facilitate research-driven and technology-based interventions, on a fast-track mode. As a paramount effort to stimulate and facilitate research and development activity towards combating COVID-19, DBT has evolved a set of Rapid Response Regulatory Frameworks in the form of following notifications:

- Rapid response regulatory framework for COVID-19 to deal with applications for development of vaccines, diagnostics, prophylactic and therapeutics dated 20.03.2020 for fast track review and approval of applications. http://dbtindia.gov.in/sites/default/files/om_covid19.pdf
- Interim guidance document on laboratory biosafety to handle COVID-19 specimens for R & D purpose dated 08.04.2020. http://dbtindia.gov.in/sites/default/files/OM_Interim_Guidance_COVID.pdf
- Rapid Response Regulatory Framework for COVID-19 Vaccine development; Checklist for application to conduct pre-clinical toxicity (PCT) studies for recombinant vaccine for COVID-19 dated 26.05.2020. http://dbtindia.gov.in/sites/default/files/Checklist_Recombinant%20Vaccine%20COVID%2019.pdf

In order to accelerate research and development pertaining to COVID-19, the Review Committee on Genetic Manipulation (RCGM) functioning in DBT has processed/considered more than 100 applications till date, on a fast-track mode. These include applications received from various Institutes, Universities and Industries on import, export, transfer, receipt of COVID-19 clinical specimens/SARS-CoV2 isolates/process intermediates, undertake research for the development of COVID-19 prophylactics, therapeutics or diagnostic platforms.

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