

Federal Guidance For COVID-19

FDA Guidance

March 18, 2020: FDA reminds the world that they have robust rules and processes for the emergency use/expanded access to test articles. Subject safety is paramount, contingencies should be made for interruptions in research (we did this).

[Coronavirus \(COVID-19\) Update: FDA issues a guidance on conducting clinical trials](#)

March 19, 2020: FDA assures the world that reports of adverse effects for COVID patients taking NSAIDs are unproven.

[FDA advises patients on use of non-steroidal anti-inflammatory drugs \(NSAIDs\) for COVID-19](#)

March 20, 2020: The FDA issued a new policy that allows manufacturers of certain FDA-cleared non-invasive, vital sign-measuring devices to expand their use so that health care providers can use them to monitor patients remotely. The devices include those that measure body temperature, respiratory rate, heart rate and blood pressure.

[Coronavirus \(COVID-19\) Update: FDA allows expanded use of devices to monitor patients' vital signs remotely](#)

March 21, 2020: FDA releases emergency and expanded access for COVID diagnostics.

[Coronavirus \(COVID-19\) Update: FDA Issues first Emergency Use Authorization for Point of Care Diagnostic](#)

March 22, 2020: FDA announces they will not be penalizing health care providers for temporarily ceasing to perform elements to assure safe use and risk and safety mitigation strategies (MRIs, liver enzyme tests, ect.) during this "public health emergency".

[Coronavirus \(COVID-19\) Update: FDA provides update on patient access to certain REMS drugs during COVID-19 public health emergency](#)

March 22, 2020: Ventilator guidance - FDA does not intend to penalize healthcare providers for limited modifications to the indications, claims, functionality, or to the hardware, software, or materials of FDA-cleared devices used to support patients with respiratory failure or respiratory insufficiency, without prior

submission of a premarket notification under section 510(k) , for the duration of the declared public health emergency only.

[Coronavirus \(COVID-19\) Update: FDA Continues to Facilitate Access to Crucial Medical Products, Including Ventilators](#)

NIH Guidance

Proposal Submission & Award Management

[NIH Late Application Policy Due to Public Health Emergency for United States for 2019 Novel Coronavirus \(COVID-19\) - NOT-OD-20-082](#)

- Institutions must submit applications or reports as soon as possible after reopening or resuming operations so that grant applications can be submitted, not to exceed the number of days the institution was officially closed or unable to submit grant applications.
- Institutions must submit a cover letter with the applications with enough detail about the delay so that NIH staff can make a determination whether circumstances justify accepting the application late.
- Institutions need not request advance permission to submit late due to this declared emergency.

[General Frequently Asked Questions \(FAQs\) - Proposal Submission and Award Management Related to COVID-19 - NOT-OD-20-083](#)

[Flexibilities Available to Applicants and Recipients of Federal Financial Assistance Affected by COVID-19 - NOT-OD-20-086](#)

- Wide variety Flexibilities allowed for awards affected by COVID interruptions.

Human Subjects & Clinical Trials

[Guidance for NIH-funded Clinical Trials and Human Subjects Studies Affected by COVID-19 - NOT-OD-20-087](#)

- Limiting study visits to those needed for participant safety or coincident with clinical care.
- Conducting virtual study visits
- Arranging flexibilities for required laboratory tests or imaging needed for safety monitoring to occur at local laboratories or clinics
- Canceling large gatherings of 50 or more people
- Limiting or suspending unnecessary travel

Animal Welfare

[OLAW Webinar: Pandemic Contingency Planning and Its Impact on Animal Care](#)

[Flexibilities for Assured Institutions for Activities of Institutional Animal Care and Use Committees \(IACUCs\) Due to COVID-19 - NOT-OD-20-088](#)

- The IACUC may institute alternatives to face-to-face meetings such as teleconference or video conferencing.
- The number of IACUC meetings may be reduced to as few as one every six months.
- The IACUC may choose to expand their use of designated member review in lieu of full committee review.

NRC

- Maximize remote working
- Deferring most travel and inspections
- **Being prepared to work with employees who may have been in contact with individuals who have tested positive for COVID-19 to self-isolate, in accordance with CDC guidance.**