COVID-19 Human Subjects-Related Federal Guidance

Institutional Review Board (IRB)/Human Research Protection Program (HRPP)-Specific Guidance

Title	Date Issued	Purpose	Link
FDA Guidance on Conduct of Clinical Trials of Medical Products During COVID-19 Pandemic	*3/18/20* *Updated 4/2/20* *4/16/20* *5/11/20* *5/14/20* *6/3/20* *7/2/20* *12/4/20*	*Provides general considerations to assist sponsors in assuring the safety of trial participants, maintaining compliance with good clinical practice (GCP), and minimizing risks to trial integrity during the COVID-19 pandemic.* *4/2/20 Update: Added Q&A 1-10* *4/16/20 Update: Added Q&A 11-17* *5/11/20 Update: Added Q&A 18-20* *5/14/20 Update: Added Q&A 21-22* *6/3/20 Update: Added Q&A 23* *7/2/20 Update: Added Q&A 24* *12/4/20: Added new Q&A 8*	*Guidance* *Related: Animal Guidance* *Bioequivalence Studies for Submission in ANDAs* *Safety Reporting Requirements for INDs and BA/BE Studies* *FDA MyStudies App for Consent*
Exception to the Single IRB Review Requirements for Certain HHS-Conducted or-Supported Cooperative Research Activities Subject to the 2018 Requirements During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency	*10/08/20*	*The exception determination allows for cooperative research, supported or conducted by HHS and subject to the 2018 requirements, not to comply with the single IRB requirement when the research is initially reviewed or ongoing during the COVID-19 public health emergency, reliance on a sIRB is not practical and the HHS division has approved the exception.*	*OHRP Guidance* *NIH Implementation (10/23/2020)*
Institutional Review Board (IRB) Review of Individual Patient Expanded Access Requests for	*6/2/20*	*Outlines review considerations for IRBs when assessing individual patient expanded access requests for COVID-19 treatments, including physician qualifications, risk and benefit to the patient, communication via assent/consent documents, and plans for monitoring adverse events. The Food and Drug Administration (FDA) encourages IRBs*	*Guidance*

Investigational Drugs and Biological Products During the COVID-19 Public Health Emergency Guidance for IRBs and Clinical Investigators: Guidance for IRBs and Clinical Investigators		*to develop procedures for single-member IRB review.*	
NSF Guidance on the Effects of COVID-19 on Human Subjects Research	*4/13/20*	*The National Science Foundation (NSF) will be accepting an IRB "review pending" determination notice in place of an approval or exemption determination for NSF awards.*	*Guidance*
OHRP Guidance on COVID-19	*4/8/20*	*Clarifies regulatory requirements and flexibility of 45 CFR 46; confirms consistency with FDA-issued medical products guidance.*	*Guidance* *Related: NIH Guidance* *OHRP Disasters Guidance* *FDA Medical Products Guidance*

Research-Related Guidance

Title	*Date Issued*	*Purpose*	*Link*
Emergency Use Authorization for Vaccines to Prevent COVID-19	*10/6/20* *Updated 2/22/21*	*This guidance provides recommendations regarding the supporting data and information required from sponsors who request Emergency Use Authorization (EUA) for COVID-19 vaccines. Key recommendations include submission of adequate manufacturing data to ensure quality data and consistency and a well-organized summary of scientific evidence to support the product's safety, effectiveness, risk/benefit profile, and adequate, approved, and available alternatives to the product.* *2/22/21 Update: Added manufacturer recommendations for modifying current EUAs due to new virus variants. For more information on the changes, see the FDA press release.*	*Guidance*

Title	Date Issued	Purpose	Link
Assessing COVID-19-Related Symptoms in Outpatient Adult and Adolescent Subjects in Clinical Trials of Drugs and Biological Products for COVID-19 Prevention or Treatment	*9/14/20*	*Outlines recommendations for sponsors initiating clinical trials evaluating drugs for the prevention or treatment of COVID-19 in outpatient setting.*	*Guidance*
Development and Licensure of Vaccines to Prevent COVID-19	*6/30/20*	*Key considerations to satisfy requirements for chemistry, manufacturing and control, nonclinical and clinical data through development and licensure, and for post-licensure safety evaluation. The FDA advises development programs to support traditional FDA approval by conducting studies to directly evaluate the ability of the vaccine to protect humans from SARS-CoV-2 infection and/or disease.*	*Guidance*
Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications for Medical Devices — Questions and Answers	*6/22/20*	*Provides answers to FAQs regarding sponsor requests for formal meetings with the FDA (conducted via videoconference), user-fee application goals and timelines (remaining committed and will adhere to previous guidance), and other regulatory and policy issues related to device development for the duration of the COVID-19 public health emergency.*	*Guidance* *Related: FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Goals* *FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals* *FDA and Industry Actions on De Novo Classification Requests: Effect on FDA Review Clock and Goals*

Title	Date Issued	Purpose	Link
Statistical Considerations for Clinical Trials During the COVID-19 Public Health Emergency	*6/16/20*	*Offers considerations to preserve trial integrity, particularly when considering study modifications, and guidance related to trial mitigation and analysis strategies, including when to consult with the FDA.*	*Guidance*
COVID-19: Developing Drugs and Biological Products for Treatment or Prevention — Guidance for Industry	*5/11/20*	*Outlines current FDA recommendations regarding phase 2 or phase 3 trials for drugs under development to treat or prevent COVID-19, including population, trial design, efficacy endpoints, safety considerations and statistical considerations for such clinical trials.*	*Guidance*
COVID-19 Public Health Emergency: General Considerations for Pre-IND Meeting Requests for COVID-19 Related Drugs and Biological Products	*5/11/20*	*Urges sponsors to submit pre-investigational new drug (pre-IND) meeting request with the FDA to facilitate faster clinical trial initiation.*	*Guidance* *Related: Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications — Questions and Answers*
Information Pertaining to Additional Safety Protections Regarding Use of Fecal Microbiota for Transplantation — Screening Donors for COVID-19 and Exposure to SARS-CoV-2 and Testing for SARS-CoV-2	*4/9/20* *Follow-up to Safety Alert issued 3/23/20*	*Requires stool and donor screening, testing, and fecal microbiota for transplantation (FMT)-recipient informed consent procedures related to transmission of SARS-CoV-2.*	*Guidance* *Related: Safety Alert*

Title	Date Issued	Purpose	Link
Investigational COVID-19 Convalescent Plasma: Guidance for Industry ***(Please note an EUA has been issued for Convalescent Plasma on 8/23/20)***	*4/8/20* *Updated 5/1/20 to remove donor requirements and clarify storage* *Updated 9/2/20 to provide information related to the FDA-issued EUA* *Updated 11/16/2020 to extend the enforcement discretion through 02/28/2021* *Updated 1/15/21 to include recommendations for inclusion of plasma donors who received the COVID-19 vaccine*	*Provides recommendations to healthcare providers and investigators on the administration and study of investigational convalescent plasma. Provides recommendations to blood establishments on the collection of COVID-19 convalescent plasma.*	*Guidance* *Related: National Expanded Access Treatment Protocol (Closed to enrollment 8/28/20)* *Implementation of Acceptable Full-Length and Abbreviated Donor History Questionnaires and Accompanying Materials for Use in Screening Donors of Source Plasma*
Responses to Top Questions From Responsible Parties Related to Coronavirus (COVID-19)	*4/2/2020*	*Addresses questions about submitting information to the ClinicalTrials.gov Protocol Registration and Results System (PRS) during the COVID-19 pandemic.*	*Guidance*

Treatment Guidance in the Clinical Setting

Title	Date Issued	Purpose	Link
Emergency Use Authorizations	*2/4/20* *Public Readiness and Emergency Prepared-ness (PREP) Act through 10/1/2024*	*To allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat or prevent serious or life-threatening COVID-19 when there are no adequate, approved and available alternatives.*	*Guidance* *Related: Adverse Event Reporting for Medical Devices Under Emergency Use Authorization (EUA) or Discussed in COVID-19-Related Guidance Documents* *Medical Devices* *Therapeutics* *Serology (Antibody) Test Performance* *Coronavirus Treatment Acceleration Program* *Emergency Use Authorizations (EUAs)* *Video Resource* *PREP Act*
Therapeutic EUAs:			
Monoclonal Antibodies	*2/9/21*	*EUA issued for monoclonal antibodies administered together to treat mild to moderate COVID-19 patients.*	*EUA*
Convalescent Plasma	*8/23/20*	*EUA issued to allow use of COVID-19 convalescent plasma, a biologic product to be used for the treatment of hospitalized patients with COVID-19.*	*EUA* *Related: Fact Sheet for health care providers and patients*

Title	Date Issued	Purpose	Link
Fresenius Medical, multiFiltrate PRO System and multiBic/multi Plus Solutions	*4/30/20*	*EUA for continuous renal replacement therapy (CRRT) to treat patients in acute care during the COVID-19 pandemic.*	*EUA* *Related: Fact Sheet for Healthcare Providers*
Remdesivir ***(Please note the EUA scope has been expanded to treat all hospitalized COVID-19 patients.)***	*5/1/20* *Updated 8/28/20*	*EUA issued to allow remdesivir to be distributed and used by licensed healthcare providers to treat adults and children hospitalized with COVID-19.*	*EUA* *Related:* *FAQs*
Fresenius Propoven 2%	*5/8/20*	*EUA for emulsion to maintain sedation via continuous infusion in patients greater than 16 years old who require mechanical ventilation in an intensive care unit setting during the 2019 coronavirus disease (COVID-19) pandemic.*	*EUA* *Related: Fact Sheet for Healthcare Providers*
Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)	*3/16/20* *Updated 5/11/20 to prioritize access and accuracy*	*Outlines policy regarding use of diagnostic and serological testing with or without an EUA, including when a state takes responsibility for COVID-19 diagnostic testing by laboratories in its state.*	*Guidance* *Related: FDA Statement* *Testing Supply Substitution Strategies* *FDA Voices* *In Vitro Diagnostics EUAs* *Serological Test EUAs*

Title	Date Issued	Purpose	Link
Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic	*3/19/20*	*Update of 2012 guidance to clarify FDA reporting expectations during a pandemic when workforces may be reduced because of high employee absenteeism while reporting may increase regarding adverse events related to widespread use of medical products indicated for the treatment or prevention of the pathogen causing the pandemic.*	*Guidance*
Alternative Procedures for Blood and Blood Components During the COVID-19 Public Health Emergency	*4/2/20*	*Provides exceptions or alternatives to certain requirements to improve availability of blood and blood components while helping to ensure adequate protections for donor health and maintaining a safe blood supply for patients.*	*Guidance*
Temporary Policy for Compounding Certain Drugs for Hospitalized Patients by Outsourcing Facilities During the COVID-19 Public Health Emergency	*4/16/20* *Updated 5/21/20*	*Addresses drug shortages used to treat COVID-19 by confirming the FDA does not intend to take action against an outsourcing facility for compounding a drug product that is essentially a copy of an approved drug.*	*Guidance* *Related: Unregistered Outsourcing Facilities* *Repackaging or Combining Propofol Drug Products* *Exemption and Exclusion from Certain Requirements of the Drug Supply Chain Security Act During the COVID-19 Public Health Emergency* *Temporary Policy Regarding Non-Standard PPE Practices for Sterile Compounding by Pharmacy Compounders Not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency*

Title	Date Issued	Purpose	Link
Temporary Policy on Prescription Drug Marketing Act Requirements for Distribution of Drug Samples During the COVID-19 Public Health Emergency	*6/8/20*	*Outlines enforcement discretion related to the distribution of prescription drug samples: collection of physical signatures upon delivery and the ability of licensed healthcare providers to request that drug samples be delivered to various locations.*	*Guidance*

Device- and Drug-Related Enforcement Policies and Guidance

The FDA does not intend to object to **limited device modifications* without submission of a 510(k) to establish substantial equivalence to a legally marketed device when those modifications do not pose **undue risk* to patients in light of the COVID-19 pandemic. These policies are in effect only for the duration of the COVID-19 public health emergency. Related guidance included in table.

**See specific guidance for examples.*

Policy or Guidance	Date Issued
Protecting Participants in Bioequivalence Studies for Abbreviated New Drug Applications During the COVID-19 Public Health Emergency	*1/15/21*
Notifying CDRH of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act During the COVID-19 Public Health Emergency (Revised)	*Original: 6/19/20 Revised: 11/25/20*
Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (Revised)	*Original: 3/20/20 Revised: 10/28/20*
Resuming Normal Drug and Biologics Manufacturing Operations During the COVID-19 Public Health Emergency	*9/10/20*
Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID-19 Public Health Emergency Questions and Answers	*8/20/20*
Enforcement Policy for Viral Transport Media During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency: Guidance for Commercial Manufacturers, Clinical Laboratories, and Food and Drug Administration Staff	*7/20/20*
Good Manufacturing Practice Considerations for Responding to COVID-19 Infection in Employees in Drug and Biological Products Manufacturing	*6/19/20*

Policy or Guidance	Date Issued
Hospital Beds, Stretchers, and Mattresses During the COVID-19 Public Health Emergency	6/10/20
Recommendations for Sponsors Requesting EUAs for Decontamination and Bioburden Reduction Systems for Face Masks and Respirators During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency	5/26/20
Supplements for Approved Premarket Approval (PMA) or Humanitarian Device Exemption (HDE) Submissions During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency	5/21/20
Enforcement Policy for Remote Digital Pathology Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency	4/23/20
Enforcement Policy for Imaging Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency	4/23/20
Enforcement Policy for Non-Invasive Fetal and Maternal Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency	4/23/20
Enforcement Policy for Telethermographic Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency	4/16/20
Enforcement Policy for Digital Health Devices for Treating Psychiatric Disorders During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency	4/14/20
Enforcement Policy for Extracorporeal Membrane Oxygenation and Cardiopulmonary Bypass Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency	4/6/20
Enforcement Policy for Remote Ophthalmic Assessment and Monitoring Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency: Guidance for Industry and Food and Drug Administration Staff	4/6/20
Enforcement Policy for Infusion Pumps and Accessories During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency	4/5/20
Enforcement Policy for Clinical Electronic Thermometers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency	4/4/20
Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency	3/30/20
Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency	3/29/20
Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency	3/25/20
Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency	3/22/20

Additional Resources

Centers for Disease Control and Prevention (CDC): Information for Clinicians on Investigational Therapeutics for Patients With COVID-19

CITI Coronavirus (COVID-19) Resources

CITI Program has complied complimentary webinars and resources to help HRPPs navigate responses to COVID-19.

FDA Resources

Provides the latest COVID-19 information from the FDA.

Coronavirus Disease 2019
COVID-19-Related Guidance
Resources for Health Professionals
Educational Resources
Contacts for Medical Devices During the COVID-19 Pandemic

HIPAA, Civil Rights, and COVID-19

During the COVID-19 public health emergency, the Department of Health and Human Services (HHS) Office for Civil Rights (OCR) has provided guidance that helps explain civil rights laws as well as how the HIPAA Privacy Rule allows patient information to be shared in the outbreak of infectious disease and to assist patients in receiving the care they need.

NIH National COVID Cohort Collaborative (N3C)

Centralized, secure enclave to store and study vast amounts of medical record data from people diagnosed with coronavirus disease across the country.

Public Responsibility in Medicine and Research (PRIM&R) Webinar: COVID-19: How HRPPs Are Preparing and Responding — A Discussion Forum

This guidance summary is updated each week on Friday. Questions, comments and additions are welcome. Please contact our Huron IRB services leadership team:

Tom Bechert: tbechert@hcg.com

Frank Conte: fconte@hcg.com

Candi Loeb: cloeb@hcg.com

Madeleine Williams: mwilliams@hcg.com

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