



EMORY
UNIVERSITY

Institutional Review Board

Research Administration

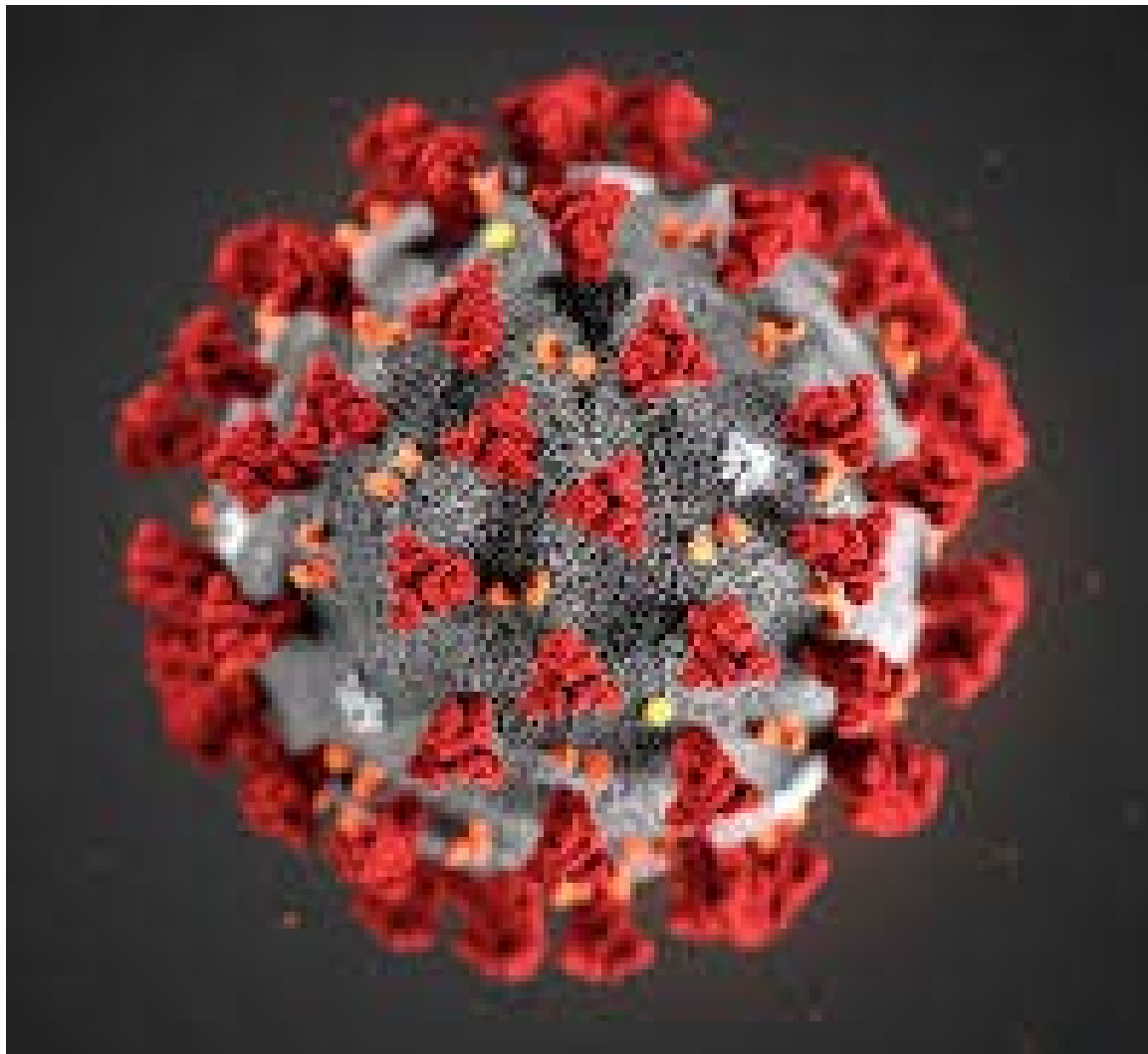
EMORY
UNIVERSITY
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Clinic & Hospital Parking



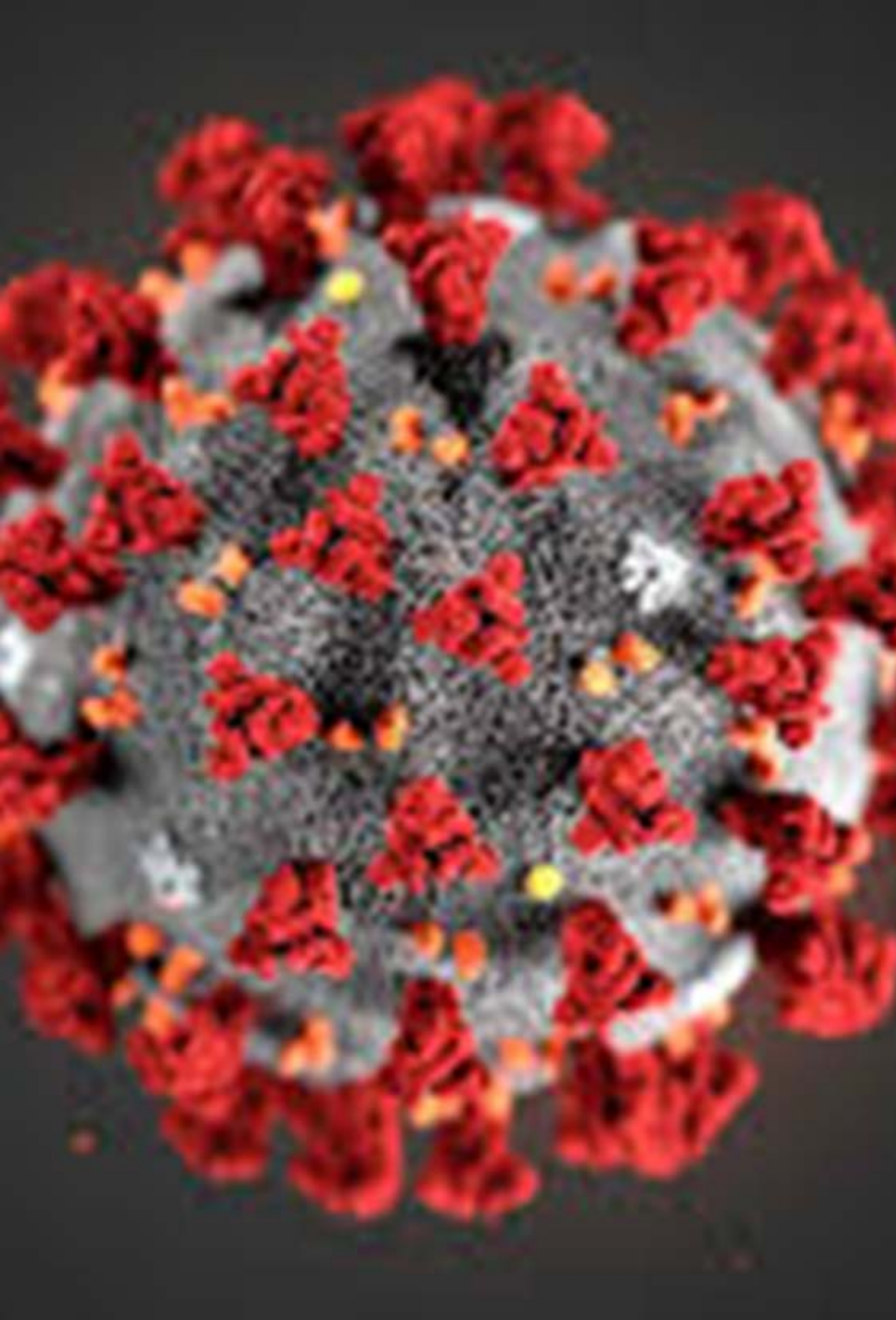
ADULT EMERGENCY





Human Subjects Research at Emory during COVID-19

CURRENT IRB
RECOMMENDATIONS AND
ECONSENT OPTIONS

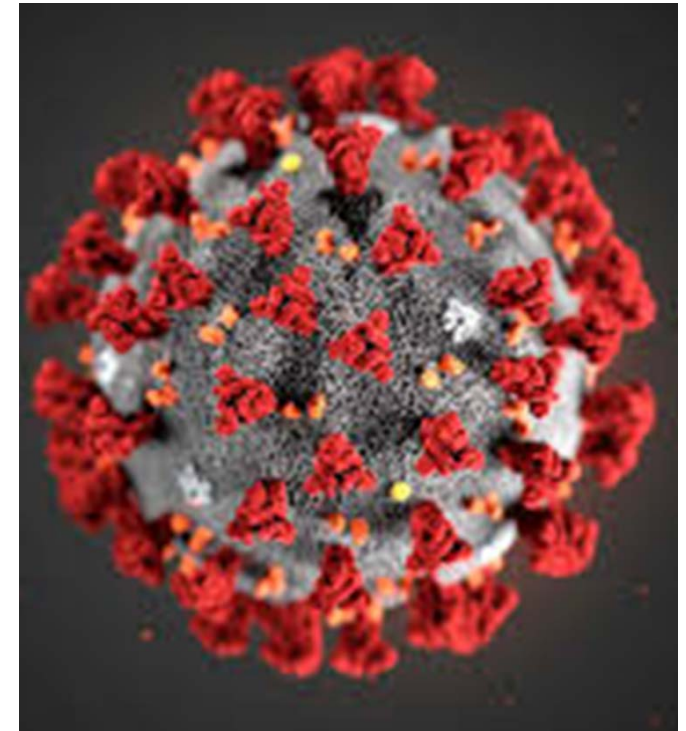


Discussion Points

- Emory Recommendations for Subjects' and Study Teams' Safety during this pandemic
- COVID-19 Emory IRB Guidance
 - Exceptions to prior IRB approval – when allowed
 - When is a Modification required?
 - External IRB Review
 - Ongoing In-Person Visits
 - If Virus Screening Is Mandatory
 - New Protocol Review
 - Emory IRB working with you!
- Current FDA Guidance-information you should know!

Discussion Points

- Electronic Informed Consent
 - RedCap functionality
- Lab Assessment Documentation during Covid-19
- Coverage of Study Visits/Procedures in Case of a Workforce Decrease: IRB considerations
- FDA Recommendations for the Management of Clinical Trials during COVID-19 Pandemic



Current Emory Recommendations for Subjects' and Study Teams' Safety during this pandemic

ORA [released guidance](#) following current [Emory](#) and [CDC](#) guidance:

- **All but essential research activities (as defined for this situation and determined at the school level) should start the ramp down, effectively immediately and completed no later than March 23.**
- This ORA Covid-19 Page includes many resources including info about Sponsored Research and deviations

COVID-19 Emory IRB Guidance – Changes to Research Prior to IRB Approval

Deviations may occur prior to IRB approval only when necessary to eliminate apparent immediate hazards

Covid-19-specific Situations:

- Actions to reduce potential exposure to COVID-19
- Providing **medically necessary study care** (including study drug) to participants in isolation or quarantine, or
- Measures to eliminate immediate hazards to research or clinical staff

Consent forms: A revised consent form is not required for urgent changes unless the change fundamentally alters what the participants consented to. You can inform participants via other means.

The IRB (and others) advise you to keep careful tracking of all protocol deviations related to the pandemic.

COVID-19 Emory IRB Guidance – Changes to Research Prior to IRB Approval

Submit a RNI within ten business days if the deviation meets IRB reporting criteria

- See table in the [Emory IRB guidance](#) document

Also follow sponsor and FDA documentation and reporting requirements

When is a Modification Required?

Modifications are required whenever:

- The changes do not meet the criteria detailed in the previous slide, or
- The criteria are met, but there is time to obtain IRB approval, or
- The changes are urgent (thus require a protocol deviation), but also need to be sustained for multiple visits/subjects.

The Modification can include: a revised version of the protocol, or simply a letter, memo or other document describing temporary changes. Include potential impact to risk/benefit/safety.

Note: If the modification will be permanent, modify your protocol or addendum as applicable (for example, you decide to keep a electronic informed consent (eIC) process you did not have before)

Adding COVID-19 screening before in-person visits	No IRB submission needed if data not used for research purposes
Using phone or telehealth instead of in-person visits, or doing home visits	RNI and/or Modification – ensure any software is compliant with Emory policy
Notifying subjects of changes to procedures/visits due to pandemic, via phone or letter (note: if email, must be encrypted)	- No IRB submission needed if communication is limited to scheduling information. - RNI and/or Modification if includes instructions for continuing any procedures at home or other sites.
New enrollment via e-Consent or verbal consent	Modification (may not occur without prior IRB approval) and by using current LITS-approved software). Please, also reference this guidance to know if you need LITS review even if using a new software.
New enrollment or re-consent via mail or fax, with same signature method as before	No IRB submission needed (unless other procedures also moving to remote)
Shipping investigational products directly to research participants	RNI and/or Modification. Consult with IDS for more information about their requirements.
Temporarily stopping subject recruitment or placing a temporary hold on all or certain study procedures.	Holds or closure to new enrollment: do NOT need to be reported via RNI; just log a comment.
	Temporary holds on all or certain study visits/procedures: RNI and/or Modification
Other deviations as deemed appropriate to eliminate immediate hazards to subjects due to exposure to COVID-19	RNI only if deviations increase the risk of harm to participants, or adversely affect the integrity of the data; Modification if changes will be sustained and conflict with the current protocol or IRB smartform.

COVID-19 Emory IRB Guidance – Quick Guide

Sponsors, FDA, and CT.gov (examples)

CT.gov:

- **Question:** Do temporary changes in clinical trial protocols necessitated by COVID-19 exigencies require updates in ClinicalTrials.gov?
- **Answer:** Yes, if a clinical trial protocol is amended such that the changes are communicated to the trial participants, then, as set forth in the regulations governing ClinicalTrials.gov (42 CFR 11.64), the information regarding the protocol in ClinicalTrials.gov must be updated within 30 days after the change is approved by the authorized IRB. [NIH COVID FAQ, Section VIII].

FDA: <https://www.fda.gov/media/136238/download> (search for “deviation”)

NIH: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-087.html> (“Guidance for NIH-funded Clinical Trials and Human Subjects Studies Affected by COVID-19”)

External IRB Review

Studies under review by an external IRB must follow the guidelines of that IRB.

Contact the analyst or customer service for your IRB of record, and/or see the following webpages for these IRB's:

- NCI CIRB: <https://www.ncicirb.org/announcements/covid-19-and-cirb>
- Western IRB (WIRB): <https://www.wcgclinical.com/changes-to-researchmade-in-response-to-covid-19/>
- Advarra: <https://www.advarra.com/about-advarra/news/impact-ofcoronavirus-outbreak-on-protocols-under-advarra-irb-review/>

On-going in person visits



If in-person visits are deemed essential by the Department/Division/School, due to direct benefit to the subject that outweighs the added risk, all possible measures should be taken to maintain as favorable a risk/benefit ratio as possible.



We will discuss this later under the “Recommendations for Clinical Trials”

When Virus Screening Is Mandatory

If COVID-19 screening is mandatory in your clinical area:

- Would not be considered part of the research procedures, therefore it does not constitute a change in the IRB-approved protocol.
- No Modification is required.
- If you wish to incorporate the screening data into your research, however, then you would need to submit a protocol modification.



New Protocol Review

As in past health emergencies, top priority new *clinical* studies can be reviewed within as little as 3 days; minimal risk research can be faster.

- Please use our [protocol templates](#) to avoid delays!!!

Urgent therapeutic studies: **Use Rapid Response policy and procedure**

- Coordinates relevant ORA units for study startup.
- Requires high-level approval.
- To request, please contact [Sherry Coleman](#) and [Robin Ginn](#)

The IRB can help with the entire submission process if urgently needed.

Central IRB reliance agreements can be expedited



Emory IRB Is Working with You!

The Emory IRB staff are all working remotely.

We are also experienced with holding Committee meetings via teleconference.

Our current university closure should not significantly impact our ability to review research, including high-priority studies and modifications.

FDA Guidance- information you should know!

COVID-19 Convalescent Plasma – Emergency INDs

(Released 3/24/2020)

- Single use of COVID-19 convalescent plasma for patients with:
 - Lab confirmed COVID-19 diagnosis and
 - Severe or immediate-life-threatening COVID-19.
 - Plasma may only be collected from recovered individuals if they are eligible to donate blood (21 CFR 630.10, 21 CFR 630.15).
 - Patients needs to be consented (use our [expanded access consent document](#)).
- Highly time sensitive requests (<4 hours): obtain verbal authorization from FDA's Office of Emergency Operations (866) 300-4374
- Not highly time sensitive requests (4-8 hour response time): complete [form 3926](#) and email to CBER_eIND_Covid-19@FDA.HHS.gov

Reference: Huron Summary of FDA Guidance Related to COVID-19

FDA Guidance- information you should know!

FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic

(Released 3/18/2020; Updated 3/27/2020)

- Provides information for IRBs, Sponsors and Investigators “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.
- Incorporated parts into our current Emory IRB guidance.
- Covers (examples):
 - Can a sponsor initiate virtual clinical trial visits for monitoring patients without contacting FDA?
 - Monitoring considerations
 - How do I obtain a signed informed consent from a patient who is in isolation and the COVID-19 infection control policy would prevent us from removing a document signed by the patient from their hospital room?
 - How should sponsors manage protocol deviations and amendments to ongoing trials during the COVID-19 pandemic? How to best capture these data?
 - Key factors to consider when deciding whether to continue an investigational product that appears to be providing benefit during the COVID-19 pandemic

Reference: Huron Summary of FDA Guidance Related to COVID-19

FDA Guidance- information you should know!

Post-marketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic.

Released: 3/19/2020 – replaces final guidance from 2012 to clarify application to any pandemic, not just influenza pandemic

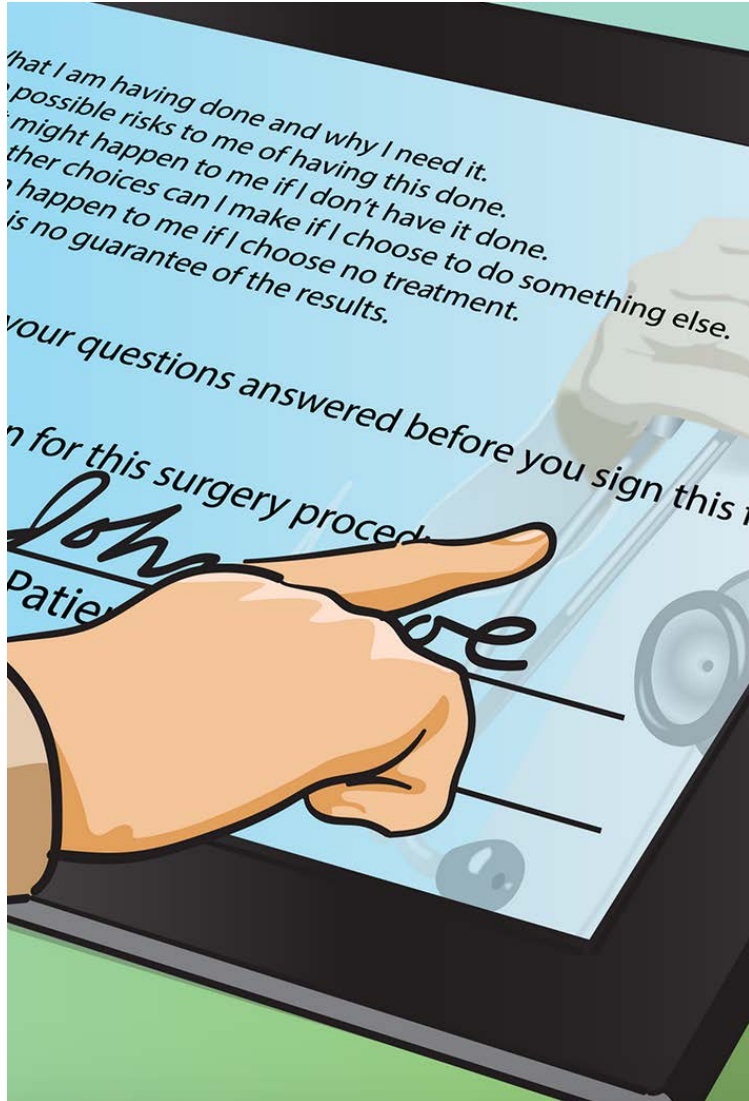
- Information about agency expectations when workforce is affected.
- FDA encourages maintaining the highest *feasible* level of adverse event monitoring and reporting

Special concerns requiring normal reporting include:

- Product-related/newly emerging safety issues
- Product problems associated with adverse events

Will need to document the WHO pandemic status in the document files

Reference: Huron Summary of FDA Guidance Related to COVID-19



Electronic Informed Consent

We have updated [our electronic informed consent \(eIC\) guidance](#) on our website to provide more detail about this process.

Consider the following:

- You will not need a eIC platform if you use email to send/receive wet-signed consent forms
 - **Encryption required** for consents revealing IIHI or other sensitive information
- If no scanner, subject can take full page picture of the last page of the signed consent form and email back (encrypted)
- Ensure you are using the correct version and that the participant has received all pages
- Save the record of the entire consent (plus the signed signature page) in your records

An illustration of a hand signing a consent form on a tablet. The form is light blue with black text. A blue arrow points to the signature line. The background is a green gradient.

Electronic Informed Consent

Electronic Signature

RedCap is currently approved for PHI
(when consent form reveals any
sensitive information/diagnosis)

DocuSign is in process of approval for
PHI

Move to electronic signature should
be approved by the IRB before
implementation

RedCap

- Already may be used for storing and/or collecting data
- Also capable of electronic informed consent
- Needs to be set up for each project individually

Example of consent:

<https://redcap.duke.edu/redcap/surveys/?s=MXERKTWJ77>

Interested in using RedCap for eConsent? Find information [here](#).



Verbal Consent due to Contagion

- The IRB can approval a verbal consent process for minimal risk research
 - Submit a modification including verbal script/information sheet, or add additional type of signature areas to existing consent
- If more than minimal risk:
 - Follow [FDA guidance](#) for use of an impartial witness and phone consent with subject (Q10) on page 15



Lab Assessment Documentation during COVID- 19

Scan lab report (or download as PDF) and email to PI (Emory email address only)

PI should sign and send the document back using the same email thread to ensure that the communication stays safe

- PI can scan or can take a picture of the whole document
- PI can also fax back if that is possible
- PI can also sign the document with Adobe Acrobat
 - Ensure the signature is FDA compliant

Coverage of Clinical Trial Visits/Procedures in Case of a Workforce Decrease

If there is no available IRB-approved, 1572-delegated team member for an **essential** study visit due to large-scale absences or remote work:

- Per FDA guidance, another MD/healthcare professional can cover (in ancillary or intermittent basis) **if** they are not making a significant contribution to the clinical data
 - No need to be added to the study or listed individually in the 1572 before this person can cover
 - Ideally, person should be CITI/GCP trained
- Must consult with PI or Co-I

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073113.pdf>

