IRB Guidance for COVID-19

Is the IRB operating as usual?

Yes, we are operating as usual. If necessary, the IRB can operate remotely and will monitor both email and voicemail regularly. Expedited studies and modifications will continue to be processed at the same rate as usual. To ensure that your COVID-19-related modifications and new studies are approved as quickly as possible, please play close attention to the submission requirements found our website: https://www.choa.org/research/institutional-review-board. The fewer times the study or modification is returned for corrections, the faster the approval will be. If a modification is of an urgent nature, please let us know by phone or email once you've submitted.

I need to screen subjects for COVID-19 before they come for a research visit. Do I have to get that approved by the IRB?

You do not need to submit a modification to the IRB in order to screen subjects for COVID-19 prior to a study visit. This screening is being implemented across the entire institution and is not research specific.

Do I have to submit a modification to the IRB in order to revise my study to address issues that arise from COVID-19?

Prior IRB approval must be obtained before initiating any change to previously approved research except when necessary to eliminate apparent immediate hazards to participants. If this occurs, report the change to the IRB within five days as a protocol deviation and submit a modification as necessary.

Can I conduct a study visit remotely instead of an in-person visit?

We encourage investigators to consider alternate methods to interact with participants, as is appropriate for their study. Submit a modification to the IRB for approval prior to implementation.

If I rely on an external IRB, what should I do?

In addition to complying with Children's institutional policies around COVID-19, you should check with your external IRB to determine what additional actions are required. Direct your IRB related questions to your external IRB. It is important to note that each IRB may implement specific guidance for studies they oversee why may be different from the Children's IRB guidance.

The NCI CIRB oversees my study. Where can I find more information about their requirements?

NCI CIRB recently posted information in response to the COVID-19 outbreak. This information can be found here: https://www.ncicirb.org/announcements/covid-19-and-cirb.

What if I need to treat a COVID-19 patient under an Emergency Use protocol?

Treating a patient in an Emergency Use situation should continue as normal. Work with the FDA to get the appropriate permissions and then submit to the IRB within five days of treatment.

Questions

Contact the IRB at 404-785-7555 or irb@choa.org.