IntegReview Response to COVID-19

UPDATE: March 31, 2020

Updated Q&A Appendix in FDA Guidance (March 27, 2020): **FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic** - Guidance for Industry, Investigators, and Institutional Review Boards

FDA updated guidance and news related to COVID-19:
https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19

For specific FDA questions you can e-mail: **clinicaltrialconduct-COVID19@fda.hhs.gov**

HIPAA Compliance and Telehealth Platforms: HHS has put out a discretion notice about what telehealth platforms are HIPAA compliant:

https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html

Things to Consider when Shipping Investigational Products to the Participant's Home:

- Are there viable alternatives other than the mail? Or private courier / Fedex?
- Drive-by pickup without coming in clinic

Verify it is not contrary with any state pharmacy licensing law.

Some products may not be appropriate for shipping to unqualified recipients (e.g. radiopharmaceuticals). Check DEA licensing for scheduled/narcotic products.

Some products may not be appropriate for self-administration (e.g. infusion, injectable). Can it be shipped to a tertiary qualified provider (e.g. home health)?

- If confirmed it is appropriate to ship, discuss with the sponsor regarding how to handle product accountability.

- Note any temperature controls and other shipping requirements needed.

If you have any questions, please contact IntegReview at integreview@integreview.com or call 512-326-3001.

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UPDATE: March 18, 2020

Today the FDA released their **FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic** - *Guidance for Industry, Investigators, and Institutional Review Boards*

Protocol Deviations:

Certain changes to research, i.e. initiating a virtual visit/telemedicine option in lieu of an in-office study visit would be a protocol deviation. However, if it does not affect the rights, safety or welfare of the participant(s) or resulted in an increased risk to participants or others, it does not need to be reported to IntegReview IRB.

Date: March 16, 2020

IntegReview IRB, like the general public, is concerned about the growing spread of the Coronavirus and we understand that many may be concerned about the status of their research participants/site staff safety, welfare, or the implication on study recruitment or conduction. This is a fluid situation and IntegReview is continuing to answer questions surrounding the conduction of research studies with our clients.

We want to reassure you that IntegReview IRB has a business continuity plan in place to ensure that there is no disruption in the services we provide to you. We have the capability to operate fully as a virtual office and manage all client accounts remotely as it is important to IntegReview that we promote the health and safety of our employees and community while maintaining business operations. IRB meetings will be planned as scheduled and meeting deadlines will remain the same as indicated on our website [click here to view Meeting & Submission Deadlines]. Changes in procedures or safety reviews may require a Full Board IRB review and staff/Board members are prepared for unscheduled meetings (online) to work quickly through these issues.

Due to this fast-evolving situation, we understand that changes may be necessary in your IRB-approved research that will require initiation without IRB approval to eliminate apparent immediate hazards to the research participants. In keeping in line with our Company policies and Federal regulations, please report these necessary changes promptly to IntegReview for IRB review; if you are unable to submit for IRB approval beforehand.

The determination of risks to research participants is the responsibility of all involved from the Sponsor/CRO, Investigator, research staff and the participant themselves. As your teams collaboratively decide on courses of action that may include: inclusion of remote or virtual study visits, remote monitoring, revisions to inclusion/exclusion criteria, protocol revisions/Informed consent revisions, updated phone screening assessments or study suspension, IntegReview IRB will be available to answer any questions.

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While minimizing the risks of transmission of COVID-19 by pausing studies will often outweigh the harms to research programs, it is important to also consider possible harms to subjects should a study be suspended for a period of time. Certain protocols involve vulnerable populations (or therapeutic areas or indications) that may present risks to research participants should the research study or interaction with the Investigator be suspended. IntegReview IRB will ask Investigators to engage in conversations with the IRB [prior to final decisions] to ensure a study suspension would not place research participants at risk of harm.

The risk of exposure to COVID-19 (of research participants, researchers and site staff) will continue to evolve based on your local Department of State Health Services and federal mandates. They may involve questions of legal liability as well as basic risk/benefit analysis. IntegReview wishes to support strategies to provide the safest and also least impactful and path forward, not necessarily the perfect solution.

IntegReview is focusing on studies on a case-by-case basis with each Sponsor/Investigator that present increased risks to research participants to help Investigators come to a solution that minimizes risks on all levels. The emphasis from the IRB is to assess the risks to the research participants.

If your research site initiates remote study visits, i.e. via telehealth platforms or in-home visits, the change in location/method of visit conduction does not need to be revised in the IC if it does not affect participant safety, welfare or confidentiality. If Sponsor-mandated, then IntegReview IRB will review these IC revisions in an expedited manner.

At this time, IntegReview is working hard to review and process all study related documents to meet client needs. Please let us know if you have special requests for high-risk situations.

In addition to protocol/IC revisions, the IRB is aware that project monitoring plans may also change. Remote monitoring is and has always been an acceptable practice. As long as the details of the monitoring do not change in respect to an increased risk to the safety of the research participant, there is no requirement to notify the IRB. Remote monitoring is a viable alternative to sending CRAs/monitors to a site. IntegReview allows e-mail, secured video conferencing, and secure restricted access to electronic medical records and file transfer as part of remote monitoring plans.

Communication is imperative during this time. If you have any questions, please contact Melanie Flores (VP, Compliance) at mflores@integreview.com or call us at (512) 326-3001.

To stay up-to-date:
World Health Organization Twitter: @WHO
Centers for Disease Control and Prevention Twitter: @CDCgov