WCG NOTICE - COVID-19 Changes in Research Updates

As a follow-up to my email on Monday, I have further updates for your study teams to help address more specific questions regarding changes to existing, ongoing studies. The recent COVID-19 outbreak has created increased concerns and ambiguity across our industry regarding how best to minimize the disruption to the trial as well as those conducting and participating in them. Many of our clients have leaned on our experts with questions related to modifications being considered to ongoing trials due to COVID-19.

You may have questions surrounding your trial regarding how to handle:

- Addition of pre-screening questionnaires to exclude persons who display symptoms of COVID-19 or are at high risk of having been exposed to COVID-19
- Decreasing protocol mandated in-person study visits
- Allowing wider visit windows
- Replacing protocol mandated in-person study visits with one or more of the following:
  - Phone calls
  - Home visits
  - Telemedicine virtual visits
- Implement digital technology to record symptoms
- Allowing blood draws at remote or commercial laboratories
- Shipping investigational products directly to research participants

*Please note that shipment of investigational products to research participants is subject to state and federal laws

If a sponsor or investigator needs to make a change to research plans in order to eliminate apparent immediate hazards to research participants, these changes can be made and then reported to the WIRB-Copernicus IRB within 5 days, as per WCG policy. Eliminating immediate hazards may include actions to reduce potential exposure to COVID-19, or to continue to provide medically necessary study care (including study drug) to participants who have been placed in isolation or quarantine because of suspected or known exposures. WCG encourages sponsors and investigators to take such steps as necessary to eliminate apparent immediate additional risks to participants.
The notification to the IRB may be a full protocol amendment, but it does not have to be. The notification of the change in research (CIR) plans may also be a memo, letter, or other document that explains the changes being made, and provides enough information for the IRB to assess the relative risks resulting from the changes. The amendment or CIR document will proceed through IRB review as per the usual process.

In an effort to help simplify things for you, if you are considering any of the possible actions as a response to COVID-19 and its impact on your trial, you will need to submit a Change of Research by clicking on the hyperlink. We have created the COVID-19 Changes in Research form specifically to address these issues for you.

I hope that this guidance helps to clarify the requirements and as always please reach out if there are further questions I can address for you.

Warm Regards,

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