Memorandum

To: COVID-19 Incident Command Centers, Principal Investigators and Research Personnel

From: Vani Nilakantan, PhD, VP Research Administration
Gayle Kusch, MSA, Director Human Research Protection Program/Research Compliance/Outside Interests and Conflict Management

Subject: Guidance, Protocols for Research at Allina during the COVID-19 Pandemic

In order to protect the health and safety of the Allina Health’s research participants, employees and the overall Allina Health community amid the rapidly changing COVID-19 situation, and in keeping with NIH and FDA guidance issued this week, Allina Health’s Research Administration and the Human Research Protection Program has instituted the following System-wide guidance until further notice:

**Research studies or Research interactions that must be paused.**

- Studies, study procedures, or activities involving person-to-person interaction with participants that have no direct significant ‘positive outcome’ and studies or study procedures that do not involve a drug or device must be paused or modified such as:
  - a. Studies deemed minimal risk (expedited or exempt)
  - b. Activities that have been deemed Not Human Subject Research Quality Improvement or Quality Evaluation

**Research studies or Research interactions that may continue.**

1. The Allina IRB will be prioritizing review of COVID-19 Protocols that involve a direct intervention and potential for direct benefits for COVID-19 patients.
2. Studies that do not involve person-to-person interactions with participants.
3. Research interactions with participants such as telephone contact, remote monitoring or remote data collection may continue.
4. Studies which offer direct therapeutic benefit (drug or device) to participants:
   - Studies that involve the administration of drugs or monitoring of devices that provide direct therapeutic benefit (drug or device) to study participants may continue. It is assumed that trials with investigational treatments, including drugs and devices, provide potential for therapeutic benefit (drug or device) and can continue. Specifically:
     - i. Enrollment of new participants as long as there is therapeutic intent.
     - ii. Study activities that can be monitored remotely by telephone or electronically, such as screening or follow-up, should be done in this way.
     - iii. For health and safety, these changes can be instituted immediately; please submit an amendment to the IRB record to indicate the temporary modifications.
The procedure for Single Patient Emergency Use of an experimental drug or device remains the same during the COVID-19 situation.

If an appropriately trained and licensed health care provider in an emergency situation determines that IRB approval for the use of an investigational drug/device at the facility cannot be obtained in time to prevent serious harm or death to a patient, the drug or device may be used without prior IRB approval. The health care provider must, within 5 days after the emergency use of the drug or device, provide written notification of the use to the IRB including the identification of the patient involved, the date of the use, and the reason for the use. For guidance or questions, please contact the Allina Health IRB Office, irb@allina.com.

Do I need to notify the IRB of a hold on study enrollment?
If the enrollment change is due to COVID-19, the IRB does not need to be notified. The IRB only needs to be notified of a hold on enrollment when the hold is due to a specific issue of the study that may impact participants.

Do I need to notify the Allina IRB of changes to study activities or study deviations due to COVID-19?
1. Changes to research procedures should be submitted to the Allina IRB via amendment form for approval prior to implementation to ensure that the changes do not impact the participants’ rights, privacy, and confidentiality of information except when such changes must be implemented for participants’ safety or welfare and there is not enough time to obtain IRB approval. If you are not able to obtain IRB approval prior to implementing the changes, a deviation and amendment form should be submitted afterwards to explain why the changes had to be implemented.
2. Study deviations should be submitted to the Allina IRB via Deviation/Exception form.
3. If your study is reviewed by an external IRB (e.g., WIRB or Advarra), please check with the IRB of record for their reporting requirements or refer to their website for additional information.

References


2. FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic https://www.fda.gov/media/136238/download


Please do not hesitate to contact us if you have any questions or concerns regarding this guidance.

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