

## **UPDATE ON COVID-19 AND HUMAN SUBJECTS RESEARCH: (last update 3/13/2020)**

Lifespan has formulated a robust response to the current Coronavirus (COVID-19) pandemic and all current information may be found at <https://intranet.lifespan.org/ncov>.

The Lifespan Office of Research Administration and the Human Research Protections Programs (HRPP), including the IRB, are committed to protecting the safety and welfare of our research participants and the greater community during the global outbreak of the coronavirus. Our goal is to help our research teams plan for how they can best accommodate any disruptions to the conduct of the research studies while maintaining key protections for our research participants. We want to emphasize that the priority must always be the safety and protection of the research participants and our research staff. The IRB and IRB staff are available to answer questions and support any necessary changes to facilitate responses to the quickly changing conditions.

The Lifespan ORA/IRB will remain fully operational, working remotely if necessary, and using our web-based site, IRBNet.

Until further notice, **all convened IRB meetings will be held via teleconferencing**. You will be provided instructions, as either a member or a presenter, for each meeting.

**For IRB research review, highest priority will be given to all inquiries, requests, applications, and modifications related to COVID-19. These submissions will be reviewed as expeditiously as possible.**

### **Interaction with Research Participants**

Effective immediately:

- All scheduled in-person interactions should be switched to remote interactions, whenever possible.
- **If an in-person interaction is required, all participants should be screened by phone in advance of the in-person contact.** Please ask the participant the following:
  - Have you traveled outside of the United States in the last 14 days?
  - Do you have any of the following symptoms: cold, cough, shortness of breath, sore throat, fever, abdominal pain, vomiting, or diarrhea?
  - Have you and/or a household member have been home quarantined by the Department of Health?
  - Have you had direct contact with any person who has been, or is ill, with a cold, cough, shortness of breath, sore throat, fever, abdominal pain, vomiting, or diarrhea?

**If the participant indicates “yes” to any of the above questions, please reschedule the appointment and direct the participant to call their physician. Please let the participant know that your actions are not considered diagnostic, but rather a way to protect the participant and others.**

- Participants should be questioned again prior to research interaction. If the participant exhibit these symptoms when they arrive for their study visit, please indicate that they should return home, call their physician, and that study personnel will contact them to reschedule the session. Please do not conduct any study procedures.

### **Prospective Human Subjects Research**

We strongly encourage the research community to consider whether proposed new human subjects research studies involving in-person participant contact and/or domestic or international travel must be submitted to the HRPP/IRB at this time. If delay of submission is not possible, researchers are advised to submit applications that include study procedures that allow for flexibility/alternatives to in-person participant contact.

### **Voluntary Suspension of Enrollment or Participation**

A Principal Investigator may elect to voluntarily and temporarily halt participant enrollment or participation. **Voluntary suspensions of each study must be reported to the IRB within 5 business days.**

### **IRB Review of modifications related to COVID-19**

- Addition of screening procedures related to COVID-19 **does not** require IRB approval. This is public health surveillance.
- Modifications of approved study procedures (remote vs in-person), as outlined above, is considered a change to research and **does** require IRB review and approval.
- Any addition of study procedures related to research **does** require IRB review and approval.
- Regulations permit changes to research without IRB approval only when necessary to eliminate apparent hazards to a participant and there is not sufficient time to obtain IRB approval. **Such changes without IRB approval must be reported to the IRB within 5 business days.**

## Submitting to IRB

- Prospective changes to approved research require a submission in IRBNet, Submission Type: Revision. These submissions will likely be reviewed by expedited procedures.
- Changes to approved research that occur without IRB approval require a submission in IRBNet, Submission Type: Protocol Deviation. These submissions will be reviewed by expedited procedures.
- Any addition of study procedures related to research requires a submission in IRBNet. Depending on the nature of the addition, review by the Full Committee may be required.
- Reminder: COVID-19 screening procedures do not require IRB notification, or modification of any research project documents.
- **Revisions and Other Events should clearly reference COVID-19 in the comments box when submitting in IRBNet.**
- **Do not include any other changes to the research in this package beyond those necessary in response to COVID-19.**



## Single Patient Expanded Access for Emergency Use

FDA expanded access is a potential pathway for a patient with an **immediately life-threatening condition or serious disease or condition** to gain access to an **investigational medical product** (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available.

- A specific form for the Emergency Use of Remdesivir has been created.
- All other uses should use Lifespan's Expanded Access submission form.
- All forms are available in the IRBNet Forms & Templates Library.

## Study Monitors

At this time, sponsors have not indicated if they will change their monitoring schedules. We ask that you find a location outside of the hospital to work with the monitors, if possible. You will need to be able to access study records remotely. If those arrangements are not possible, you must screen the monitors in the same fashion as study subjects (see above), escort them to your research area, and limit their time at Lifespan. Our guidance on this subject may change as we have more information.

Questions or Contacts:

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