Phase 3 Tier 2 Research Continuation Petition Form

In Phase 3, Tier 2 studies (defined as protocols with moderate direct benefit to research participants which if stopped, may pose a risk to the research participant,) must cease in-person research-related activities. However, researchers can petition the IRB for continuation of in-person research-related activities. This petition serves as that request. In order for the IRB to grant the petition, the researcher must provide a compelling reason as to why the continuation of in-person research-related activities are in the best interest of the participants.

The PI must submit this completed form as a Amendment via Further Study Action in the eHIRB system. The form should be uploaded in the Finalize Application, Additional Documents. When the PI submits the Amendment, please provide the following language in Section 1 (General Information) Question 1 as the summary of changes:

“COVID-19 Phase 3 Tier 2 continuation request. This is a petition for in-person activities to continue for this research”.

The completed form must be uploaded to the Finalize Application, Additional Documents of the application. Please note, if this petition is incomplete, it may cause a delay in the review process.

Please answer the following:

1. IRB Application Number:

2. PI Name:

3. Provide the date of the next expected in-person encounter:

4. Do you have adequate staff for continuation of the in-person related research activities?

5. Do you have sufficient materials/supplies for continuation of the in-person related research activities?

6. Please explain, in detail, why the continuation of in-person research related activities is in the best interest of the participants. Please consider whether the risks of exposure to COVID-19 impacts this assessment.

7. How will your team ensure the in-person research-related activities are conducted in a safe manner that protects subjects, researchers and the community? Please explain. In doing so, please address all the following that apply:

   o Requirement for research participants to leave their home
- Requirement for research participants to be in a group setting (focus groups, group training, waiting rooms with multiple patients)

- Research protocols targeting participants at higher risk for COVID complications (ex. elderly, immunocompromised, etc.)

- Requirement for research participants to engage in research activities beyond their usual clinical care activities

- Safety of research staff in terms of exposures to research participants/families who might have COVID-19

- Whether the research protocol requires effort that might need to be directed to high demand area for clinical care related to COVID-19 (ex. not starting research protocol that requires beds and/or clinical personnel who care for patients with severe respiratory distress)