PROTOCOL APPROVAL WITH MODIFICATIONS

DATE: 9 Jul 2019

TO: Morna Dorsey, MD, MMSc

PROTOCOL: Horizon Therapeutics - 640-2019-002, Uncovering Treatment Disparities in Chronic Granulomatous Disease (Pro00036845)

APPROVAL DATE: 2 Jul 2019

EXPIRATION DATE: 2 Jul 2020

IRB APPROVED DOCUMENTATION:

- Consent Form: Informed Consent Form and CGD Survey (Advarra IRB Approved Version 3 Jul 2019)
- Recruitment Material:
  - Postcard: “Chronic Granulomatous Disease (CGD) Survey” (Not Dated)
  - Website: “Chronic Granulomatous Disease (CGD) Survey” (Not Dated)
  - Pre-notification Email (Not Dated)
  - CGD Site Post 1 (Not Dated)
  - August eNewsletter (Not Dated)
  - Invitation Email (Not Dated)
  - Facebook Post 1 (Not Dated)
  - Twitter Post 1 (Not Dated)
  - CGD Site Post 2 (Not Dated)
  - Reminder Email 1 (Not Dated)
  - Facebook Post 2 (Not Dated)
  - Twitter Post 2 (Not Dated)
  - CGD Site Post 3 (Not Dated)
  - Facebook Post 3 (Not Dated)
  - Twitter Post 3 (Not Dated)
  - Reminder Email 2 (Not Dated)
  - September eNewsletter (Not Dated)

The IRB approved the above referenced protocol and your site with the modification listed below on 2 Jul 2019:

- Revisions to the Informed Consent Form and CGD Survey
On 3 Jul 2019, the IRB reviewed and approved additional revisions to the Informed Consent Form and CGD Survey.

The IRB granted a Waiver of Documentation of Consent.

The IRB reviewed the project in accordance with the 45 CFR Part 46, Subpart D Federal Regulations which provide for additional protections for children as research subjects.

The IRB determined that the research study meets the criteria found in the risk category described as follows:

- 45 CFR 46.404: “Research not involving greater than minimal risk.” Permission of one parent is required.

The above referenced material is available on your Advarra CIRBI Platform under the “IRB Issued Documents” tab.

If there are any changes to the IRB approved material, IRB approval will be needed prior to use. This includes changes in relative size and type of font in the material to be viewed by potential subjects.

If the study is expected to last beyond the approval period, you must request and receive re-approval prior to the expiration date noted above. A report to the Board on the status of this study is due prior to the expiration date or at the time the study closes, whichever is earlier. It is recommended that you submit status reports at least 4 weeks prior to your expiration date to avoid any additional fees or lapses in approval.

Approved investigators and sites are required to submit to Advarra for review, and await a response prior to implementing, any amendments or changes in the protocol; informed consents; advertisements or recruitment materials ("study-related materials"); investigators; or sites (primary and additional).

Approved investigators and sites are required to notify Advarra of the following reportable events, including, but not limited to: unanticipated problems involving risks to subjects or others; unanticipated adverse device effects; protocol violations that may affect the subjects’ rights, safety, or well-being and/or the completeness, accuracy and reliability of the study data; subject death; suspension of enrollment; or termination of the study.

Please review the IRB Handbook located in the “Reference Materials” section of Advarra CIRBI™ Platform (www.cirbi.net). A copy of the most recent IRB roster is also available.

Thank you for selecting Advarra IRB to provide oversight for your research project.