**Draft Investigator to Participant Letter for IRB Review and Approval**

**Date: <insert date of sending>**

**Re: Pfizer Protocol Study C4591001 (COVID-19 Vaccine Study) Successful Interim Analysis**

Dear Participant:

On November 9, 2020, Pfizer and BioNTech announced the results of an interim analysis for the COVID-19 vaccine trial that you are participating in. As background, throughout the study an independent group of experts, called a Data Monitoring Committee or DMC, check the safety and results of the study at planned timepoints to make recommendations on whether the study should continue or stop.

While this is only an interim analysis and not the full study results, this first analysis of the data collected so far showed that the study vaccine is effective at preventing COVID-19 disease in adults who have not been diagnosed with COVID-19 before. The DMC has recommended that the study should continue as planned.

It is important to continue collecting safety and efficacy data to confirm whether the study vaccine meets all of the criteria for potential authorization or approval by regulatory bodies. We appreciate your ongoing participation in this trial, such as planned office visits, logging in your eDiary and reporting any changes in health, including potential COVID-19 symptoms. Please also follow the COVID-19 precautions for your area.

We know that access to a potential vaccine, if an Emergency Use Authorization (EUA) or similar approval is granted, is top of mind for many trial participants. Pfizer and BioNTech are actively exploring potential ways to change the study to create a process that would allow interested participants in the placebo group who meet the eligibility criteria for early access in their country to “cross-over” to the vaccine group in the study. To make a change like this, the companies would first need input and approval from regulatory authorities. We will update you as we have more information on this.

Thank you again for making a difference by being a part of this study. It is only through the efforts of volunteers like you that reaching this important milestone and developing a potential vaccine against COVID-19 is possible. As always, please don’t hesitate to reach out to me or the study team at <insert organization> with any questions or concerns.

<Principal Investigator Name>

<Institution>