IRB#: \_\_\_\_\_\_\_\_ Protocol #: \_\_\_\_\_\_\_\_\_\_\_ Participant Name­­­­­­­­­­:

Date of Birth: Medical Record #:

Please **INITIAL** next to **“Yes” or “No”** by each line as appropriate **and include additional details in Notes section below.**

|  |  |  |
| --- | --- | --- |
| Yes | No | *COVID Information Sheet for Participants* has been provided to Participant and discussed with time provided for questions.  Version: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date Reviewed:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Reviewed via: □ Phone □ In-Person |
| Yes | No | Risk analysis for continued participation (including discussing anticipated benefits and risks of attending in-person study visits in the context of the COVID-19 pandemic) performed. |
| Yes, If yes, describe direct benefit of participation in Notes below. | No | Does the participant fall into any of the nine high-risk groups for severe outcomes with COVID-19 (below)?   * [People 65 years and older](https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/older-adults.html) * People who live in a nursing home or long-term care facility   People of all ages with [underlying medical conditions, particularly if not well controlled](https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/groups-at-higher-risk.html), including:   * People with chronic lung disease or moderate to severe asthma * People who have serious heart conditions * People who are immunocompromised   + Many conditions can cause a person to be immunocompromised, including cancer treatment, smoking, bone marrow or organ transplantation, immune deficiencies, poorly controlled HIV or AIDS, and prolonged use of corticosteroids and other immune weakening medications * People with severe obesity (body mass index [BMI] of 40 or higher) * People with diabetes * People with chronic kidney disease undergoing dialysis * People with liver disease |
| Yes | No | All questions and concerns were addressed to the satisfaction of the participant. The PI or Sub-I was available for questions prior to and during discussion. |
| Yes | No | Outcome: Will the participant continue their participation in the study? |

The details of participation in this research study in regards to COVID-19 risk and benefit were discussed with the participant (or participant’s LAR), including risks of breaking social distancing. The IRB-approved COVID Information Sheet was discussed in detail and all participant questions were answered.

Notes:

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Signature of Person Leading Discussion Date Time