Study Number:

Site Number: *<insert>*

Subject Number: *<insert>>*

<Instruction: Study, Site and Subject number for inclusion where required>'

Supplementary Subject Informed Consent to Enable Remote Data Verification

Dear Study Participant,

You are likely aware of the ongoing COVID-19 (Coronavirus) outbreak and the growing emergency measures that are being put in place to limit the spread of the outbreak, including government and institutional restrictions. As you are participating in a clinical trial, these restrictions may impact you and/or the study centre you would normally visit for study participation.

This clinical trial, like most others, requires study monitor(s) (people working for or on behalf of the trial Sponsor) to visit the study centre to review the clinical trial data to verify study procedures have been followed and the study data have been entered correctly in the study records. This process is called 'data verification'. An important part of this data verification includes confirming in a timely manner that the parts of the clinical trial that relate to protecting patient safety and wellbeing are properly performed at the study centre. Due to the coronavirus outbreak, these monitors may not be able to travel to or access the study centre in person to perform this important task.

We are therefore contacting you on behalf of the sponsor of the clinical trial to request your consent to enable the monitors to view your data and medical records remotely. The monitors will access your personal information in the same way that they would have accessed it if they were on site in order to verify the trial procedures you have undertaken and make sure any results are recorded correctly.

Whether your medical files are reviewed at the study center or remotely for the purposes of the study, your records will be kept secure during this process. If your medical files are reviewed remotely, the monitor will securely destroy all copies of your medical records after the review is completed.

If you are not able to visit the study centre to sign this form, the study centre staff will contact you directly and provide you with this information. Verbal consent may be taken over the phone and recorded within your medical records. Your consent in writing may be obtained remotely or at your next site visit.

Who can I contact if I have questions about this?

If you have any questions or concerns about the additional information presented in this information sheet, you should contact the study doctor or a member of the research team at the study centre, as outlined in your original consent form or [INSERT PHONE NUMBER].

If you choose not to agree to this process, it will not impact your rights, you will incur no penalty, and you may continue to take part in the study in accordance with your original consent form. You may revoke your decision to remote monitoring at any time without consequence.

Thank you for reading this information.

By signing this consent form, I confirm the following:

- I have read and understand the information provided and have had enough time to think about this request.
- I have had enough time to ask questions about the information and I am satisfied with the answers provided.
- I understand that I will receive a signed and dated copy of this consent form to keep for myself.
- I understand that I may also be contacted later for my permission in connection with this or any other study-related matters.

By signing this form, I voluntarily agree to allow monitors to verify my data remotely, as set out in this information sheet and consent form.

Printed Name of Participant:

Signature of Participant: Date:

Legal Representative Name (if applicable): *

Date:

Legal Representative Signature (if applicable):

Relationship to Participant:

*A Legal Representative will sign for participants who are not legally capable of providing consent for themselves.

Investigator/Authorized Designee:

- ✓ I have fully and carefully explained the information to the person named above and confirm that, to the best of my knowledge, they clearly understand the nature, risks, and benefits of agreeing to permit remote data verification.
- ✓ I confirm that I gave them all opportunities to ask questions about the information, and that I answered all the questions they asked correctly and to the best of my ability.
- ✓ I confirm that they have not been forced into giving consent, and that they have given their consent freely and voluntarily.
- ✓ I confirm that they will receive a signed and dated copy of this information sheet and consent form.

Printed Name of Person Obtaining Consent:

Signature of Person Obtaining Consent: Date:

Witness Signature (if applicable)**

I confirm that the information sheet and consent form, and any other written information, was accurately explained to, and apparently understood by, the participant or the participant's legally acceptable representative, and that informed consent was freely given by the participant or the participant's legally acceptable representative.

Printed Name of Witness:

Signature of Witness: Date:

**A witness signs when the information sheet and informed consent form has been read to the participant – (i) in addition to the participant or (ii) in lieu of the participant – for participants who are legally capable of providing consent, but unable to read or unable to read and write.