NHS
Cambridge
University Hospitals
NHS Foundation Trust

Date

Dear Dr *Name,*

Re: Participant name:
Date of Birth:
Hospital Number:
Address:

RE: Multi-Arm Therapeutic Trial in Pre-ICU patients admitted with Covid-19 Repurposed Drugs (TACTIC-R)

Selected Arm: Baricitinib

I am writing to inform you that your patient has agreed to participate in the above clinical trial at local hospital name.

TACTIC-R is a multicentre, parallel arm, open-label randomised controlled trial sponsored by Cambridge University Hospitals NHS Foundation Trust. The aim of the trial is to identify if immunomodulatory drugs can lower the overactive immune response that has been observed to drive the severe lung and other organ damage in COVID-19 patients at late stage 1/early stage 2 disease. Additionally, risk markers will be used to monitor disease progression in response of the therapeutic agents, thereby aiming to reduce the disease progression.

More specifically, this trial is evaluating the efficacy of the interventions of baricitinib or ravulizumab, compared to standard of care treatment. **Your patient has been selected for the baricitinib arm.**

BARICITINIB

As mentioned earlier, your patient will receive baricitinib. Baricitinib is a selective and reversible inhibitor of Janus kinase JAK1 and JAK2 and is associated with an increased rate of infections such as upper respiratory tract infections, hypersensitivity and viral reactivation. Baricitinib will not be given to patients with active tuberculosis. The risks and benefits of treatment with baricitinib will be carefully considered prior to initiating therapy in patients. If adverse events are reported baricitinib therapy will be temporarily discontinued, the patient will be monitored carefully, and therapy will be resumed only if appropriate. Patient will

receive 4mg of baricitinib PO (2 x 2mg tablets, once daily) on days 1-14. Common side effects of each intervention are as follows:
Baricitinib - Upper respiratory tract infections, hypercholesterolaemia, herpes zoster, herpes simplex, gastroenteritis, urinary tract infections, pneumonia, thrombocytosis, nausea, ALT increased ≥3 x ULN and rash. Most of these side effects are attributable to prolonged use. The drug has a short half-life (1 day) and risks will rapidly reduce once treatment ends.

For further information on the trial, I have enclosed a copy of the Participant Information Sheet for your reference, however, if you have any queries or require further information please contact the trial team (Insert local contact details including contact number and website if available).

In the event of an emergency please call:
Insert emergency telephone number which must match the telephone number on the PIS

Should you have any concerns about your patient participating in the trial, please feel free to contact our trial team.

Yours Sincerely,
PI name

Trial Team Contact Information:
Local Contact Name
Hospital
Role
Telephone number

Encs: Participant Information Sheet, version *(insert version number)* dated *(insert date)*