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To whom it may concern

16 March 2023

ISARIC/WHO Clinical Characterisation Protocol for Severe Emerging Infections

IRAS IDs England & Wales 126600; Scotland 227982

I am writing to confirm on behalf of the Sponsor that reliance on Regulation 3 of the Health Service (Control of Patient Information (COPI) Regulations 2002) for access to routinely collected clinical data and personal identifiers is relevant and appropriate for work undertaken as part of this project.

Regulation 3 concerns Communicable disease and other risks to public health and can be reviewed at https://www.legislation.gov.uk/uksi/2002/1438/regulation/3/made.

The protocol is consistent with

3(1) b. Recognising trends in such diseases and risks

and

3(1)d monitoring and managing—

- (i) outbreaks of communicable disease;
- (ii) incidents of exposure to communicable disease;
- (iii) the delivery, efficacy and safety of immunisation programmes;
- (iv) adverse reactions to vaccines and medicines;
- risks of infection acquired from food or the environment (including water supplies);
- the giving of information to persons about the diagnosis of communicable disease and risks of acquiring such disease

Any communications relating to the Sponsor position should be directed to the undersigned.

Yours faithfully

Taxen Yellam

−DocuSigned by:

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