

CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS

SAFETY REPORT TO RESEARCH ETHICS COMMITTEE

Please indicate which type(s) of safety report you wish to notify with this cover sheet (tick all that apply). Use a separate sheet for notifications relating to different trials. Please send by email to the main REC for the trial concerned together with enclosures. For further guidance see: <http://www.hra.nhs.uk/research-community/during-your-research-project/safety-reporting/>

1. Expedited report(s) of SUSAR in the UK

Notify only Suspected Unexpected Serious Adverse Reactions occurring in the concerned trial at a UK site. SUSAR reports must follow the ICH E2B format.

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2. Annual safety report / DSUR

ASRs must follow the ICH E2F format for Development Safety Update Reports (DSUR). Include a global list of all SSARs (Suspected Serious Adverse Reactions) related to the IMP and occurring in the reporting period.

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3. Other

For example, report of Data Monitoring Committee or other safety review.

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Full title of study:	RECOVERY – Randomised Evaluation of COVID-19 Therapy
EudraCT number:	2020-001113-21
Research sponsor:	University of Oxford
Name of Chief Investigator:	Prof Peter Horby
Name of main REC:	Cambridge East
Main REC reference number:	20/EE/0101

Contact details for person making this notification

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National Research Ethics Service

Date of this notification:	16-Apr-2021
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List of enclosed documents

Please list each report submitted with this notification (insert extra rows in table as required).

1. Expedited SUSARs (UK only)

Sponsor's report no. / reference	Trial site	Date SUSAR first reported to sponsor	Is this a 7 or 15 day report?
RECOVERY SUSAR008	University Hospital Birmingham	31-Mar-2021	15 day report

2. Other reports

Type of report	Date of report

Acknowledgement of receipt by main REC (please insert name):

The [] Research Ethics Committee acknowledges receipt of the above.

Signed:	
Name:	
Position on REC:	
Date:	

Signed original to be sent back only to the sponsor (or other person submitting the report).

Copy to be kept for information by main REC.