



Dear Site teams for the PROHIBIT-ICH trial,

We know that the Covid-19 situation is causing considerable anxiety, distress and disruption. Both our university and hospitals are facing a high and unpredictable challenge, including major disruption of teaching, research and our clinical services.

Our priority is to ensure the safety of participants and researchers in the PROHIBIT-ICH trial. We also aim to maximise the quality and completeness of follow-up data for participants who have already enrolled in the trial.

We are aware that some R and D teams and Trusts have already limited or suspended research activities. Clearly any face to face contact will need to be minimised, and as much data as possible should be collected remotely by telephone or by post.

Our trial management team will meet to develop a clear plan as soon as possible.

Further guidance relevant to researchers may also be found at:

MHRA Blog: Advice for Management of Clinical trials in relation to Coronavirus. MHRA are aware that there are challenges arising in relation to Coronavirus and the effect this is having on the conduct of clinical trials. They recognise the difficulties this creates for managing trials and would like to offer some advice. Read the new post:
<https://mhrainspectorate.blog.gov.uk/2020/03/12/advice-for-management-of-clinical-trials-in-relation-to-coronavirus/>

HRA: COVID-19: Guidance for sponsors, sites and researchers This guidance relates to Research Ethics Committee (REC) and NHS arrangements. This is a rapidly evolving situation and guidance will be updated in response to feedback. Please check back here for updates.

<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/covid-19-guidance-sponsors-sites-and-researchers/>

Finally, **could you please update us on any local restrictions or advice regarding conduct of trials in general, and PROHIBIT-ICH recruitment and follow-up in particular?**

Best wishes,

Maja Dabagh

Clinical Trial Coordinator for PROHIBIT-ICH