PROHIBIT-ICH COVID-19 Contingency Plan

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Purpose: This document provides guidance to all PROHIBIT-ICH research sites about how to manage trial-specific research activities during the COVID-19 pandemic.

Recruitment of new participants: <u>suspended until further notice</u>

- Please keep a screening log of potentially eligible patients for later recruitment.
- Once UK Government restrictions are lifted and there are MRI scanning facilities available for the baseline visit, recruitment can recommence.

3-month follow-up (Visit 2): <u>to be performed remotely by each site</u>

- 24-hour ABPM should still be performed by each participant; fitting can be performed by the participant or carer by following the video instructions on the PROHIBIT-ICH website www.prohibit-ich.org.uk and with telephone or video call guidance (if the participant has facilities available) from the Oxford BP Monitoring Team.
- Participants should continue to use pre-paid envelopes to return the 24-hour ABPM equipment to the Oxford team. This may require individual solutions for individual participants; please contact the Oxford team by email for guidance in advance. If participants show signs of fever or cough/shortness of breath, please instruct them to place the equipment into two bags prior to sending in the pre-paid envelope.
- Cognitive assessment is to be performed using a 22-point Telephone-MoCA (i.e. the MoCA items not requiring the use of a pencil and paper and/or visual stimulus).

12-month follow-up (Visit 3): <u>postponed</u>

- The 12-month follow-up visit should be performed as close as possible to the scheduled date, once restrictions are lifted. The MRI scan and 24-hour ABPM should happen on the same date, with the e-CRF completed at that time.

Participant Safety

- Please continue to report SAE's as outlined in the protocol.
- Where capacity issues may prevent timely reporting of SAE's, they should be reported as soon as possible after the issue is resolved and the delay recorded as a protocol deviation.

Relevant Guidance

- Guidance about COVID-19 for sponsors, sites and researchers has been provided by the HRA. Section 3.2 is relevant to sites: <u>https://www.hra.nhs.uk/covid-19-research/covid-19-guidance-sponsors-sites-and-researchers/</u>