Subject: IRAS: 284229; Notification of Amendment Category A

Dear participating organisations,

RE: IRAS: 284229; FALCON C-19; Amendment 18

We have submitted an amendment for the above referenced study. Attached is the HRA and HCRW Approval together with the amendment package, including the amendment tool. Please read the documents and amendment tool carefully as these provide information on how this amendment should be implemented, as well as what the amendment entails. Amendment documents can also be found here: <https://www.condor-platform.org/condor_workstreams/falcon/falcon-regulatory-docs>

**When will this amendment be implemented?**

The completed amendment tool has categorised this amendment as **category** **A**. In line with the [UK wide policy on the handling of amendments](https://www.myresearchproject.org.uk/help/hlpamendmentsresearch.aspx), your site has 35 calendar days from the date of this notification to raise an objection about the amendment. If we do not hear from you by Friday 22nd January, 2021, we will assume that the amendment may be implemented at your site. If you need more time to consider the amendment please contact us prior to the 35 day deadline and we will assist with any queries you may have.

**What is the impact on research activities at sites?**

This amendment does not impact the research activities undertaken at participating NHS organisations. The only document that has changed to be used in NHS organisations is the new version of the protocol (v1.6) however, the changes do not change the research activities being undertaken within the organisation. The new Participant Information Documents are for use in Work Streams B and C, **not** for Work Stream A (in-hospital).

**Is there any impact on funding/agreements?**

This amendment does not impact the funding/agreement that have previously been agreed.

**What is the HRA and HCRW Approval status of the amendment?**

If you are able to notify us ahead of the above date that you are able to accommodate this amendment it will enable us to implement sooner.

If you need to discuss the impact of the amendment at your site please do not hesitate to contact me at [FALCONstudy@mft.nhs.uk](mailto:FALCONstudy@mft.nhs.uk)

Kind regards

Eloïse Cook