9th April 2025

Dear REMAP-CAP sites,

Please do not adapt and localise the PIS/CFs yourselves – this will be done by the Trial Management team as per our updated process. This is due to errors with adapting/localising various sections of PIS/CFs in the past relating to domains/interventions/side effects etc. leading to patient consent findings. We responded to the MHRA with a CAPA.

We will provide sites with adapted, localised, locked pdf versions of PIS/CFs once R&D approvals are received. If you could provide your Trust Logo and contact/PALs details in advance that would be great otherwise we will be requesting these from you.

Kind regards

REMAP-CAP Team