

10th November 2020

CIC/RES/2020/023

#UPDATE COVID-19

Dear valued Sponsors and CRO,

Greetings from CIC.

COVID-19 INFORMATION: IMPLEMENTATION OF CONDITIONS OF CONDITIONAL MOVEMENT CONTROL (PKPB) IN ALL STATES IN PENINSULA MALAYSIA EXCEPT PERLIS, PAHANG AND KELANTAN STATES FROM 9 NOVEMBER 2020 TO 6 DECEMBER 2020

The government of Malaysia has announced the implementation of conditions of conditional movement control (PKPB) in all states in peninsula Malaysia except Perlis, Pahang and Kelantan states from 9th November 2020 to 6th December 2020. CIC management has decided to postpone all visits for monitoring, auditing and visitor access to Clinical Investigation Centre (CIC) UMMC as a precaution to reduce workplace transmission of Covid-19 until 6th December 2020. However, CIC would suggest monitoring done by a phone call on the availability of the study team. Kindly arrange with the study team.

As Work from Home (WFH) is in place, CIC staff will work from home on a rotational basis. Sponsor and CRO is advised to email the PIC to communicate efficiently.

Additional information:-

1. CIC would suggest conducting SSV and SIV virtually using platforms like ZOOM or Microsoft Team or Google meet.
2. Clinical trial patient visits will proceed as usual.
3. New study feasibility will proceed as usual.
4. CIC Legal Officer will notify the Sponsors/Collaborators to execute the Agreement by Digital Signature/ e-signature and send the PDF copy of the partially executed agreement by email.
5. For any on-going Clinical Trial (CT) that requires remote monitoring access, the said study requires to have a fully executed amendment of Clinical Trial Agreement (CTA)/ Clinical Research Agreement (CRA) relating to the said matter.
6. For any on-going Clinical Trial (CT) that requires remote monitoring access, must notify to UMMC Ethics Committee (EC).

We shall send an update about the monitoring, auditing and visitor access to CIC regularly.

Please do not hesitate to contact us if there is any further query.

Thank you.