

15th June 2020  
CIC/RES/2020/018

#UPDATE COVID-19

Dear valued Sponsors and CRO,

Greetings from CIC.

### **RCMO POST COVID-19 INFORMATION**

Malaysia has entered the recovery phase of control movement order (RCMO) starting from 10th June 2020 till 31st August 2020 hoping to further bring down the infection figure. At the current stage, many restrictions have been loosened by the government to boost economic growth. In echo to the RCMO, UMMC higher management has released a circular (SP PPU: 206/2020), all services will be fully operational, and no more rotation and work-from-home (WFH) systems will be implemented. However, it may be considered in limited circumstances as required by the welfare of the staff as specified in the Public Service Department's Distribution Letter PSD (S) 256/6/31 JLD.6 (6) dated May 2, 2020. CIC staff will start working from the office fully from 15th June 2020 onwards.

The SOP is systematically identified and reviewed to ensure all activities, situations, and processes are controlled to contain further spreading of COVID-19. The process for applying for Clinical Trial On-Site Monitoring Access Information has been uploaded in [CIC UMMC website](#) and [CIC FB](#) with the title "RCMO Post Covid-19 Standard Operating Procedure (SOP): Receiving visitors from an external organization to CIC".

#### **Procedure**

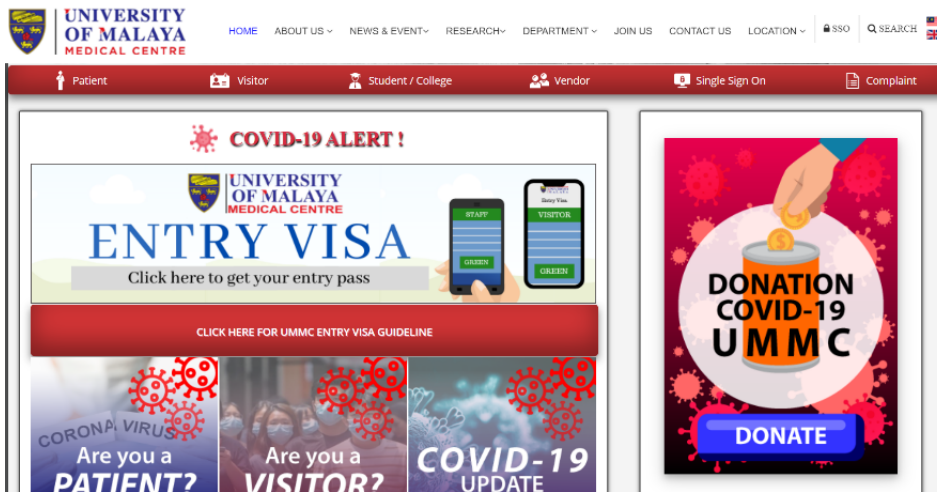
Kindly follow the process below for applying for Clinical Trial Monitoring Access Information.

#### **Step 1: Write an email to the Training & Facility Unit of Clinical Investigation Centre (CIC)**

1. Firstly, write an email to Ms Hanis Hafizah from Training & Facility Unit of Clinical Investigation Centre (CIC) ([hanishafizah@ummc.edu.my](mailto:hanishafizah@ummc.edu.my)) for approval 1 (ONE ) week before the visit date. This process is effective starting from 16<sup>th</sup> June 2020 and previous visit approval by HOD of CIC has remained unchanged.
2. Details of the visit must be stated in the email as below,
  - a. Purpose,
  - b. Dates of visit,
  - c. Area to be accessed in CIC or
  - d. Required to visit other UMMC facilities.
3. Ms Hanis Hafizah will approve the visit request through email notification in THREE (3) working days.
4. Approval of a visitor is based on monitoring room availability to maintain 1-meter social distancing within CIC premises. CIC will be maintaining 2 visitors per monitoring room.
5. Training & Facility Unit staff shall update the Google drive of the visitors for internal communication.

#### **Step 2: UMMC Visa application**

1. Please visit the following website (<https://www.ummc.edu.my/>) or by scanning the given QR code below to complete for UMMC Visa application.



IMBAS DI SINI UNTUK



**Visa Kemasukan**  
Pusat Perubatan  
Universiti Malaya

2. The Visa permission valid for one day only and it will be expired at 11:59 pm, therefore a new Visa will need to be applied on the day you are coming to UMMC.
3. Please choose “visitor category” and proceed to answer the question which follows.
4. Please use the following examples to indicate the purpose of the visit:
  - a. Monitoring Visit at Clinical Investigation Centre, Department of Research, Development & Innovation.
  - b. Site Selection Visit at Clinical Investigation Centre, Department of Research, Development & Innovation.
  - c. Site Initiation Visit at Clinical Investigation Centre, Department of Research, Development & Innovation.
  - d. Site Audit Visit at Clinical Investigation Centre, Department of Research, Development & Innovation.
5. Kindly screenshot the approved visa for inspection at the entrance of UMMC.

**Step 3: Receiving visitors from an external organization to CIC**

1. During visit day, Facility & Training unit staff at the counter will check the entrance visa of UMMC and shall perform temperature measurement based on details verification in Google drive for approval.
2. The visitor should bring own mask and hand sanitizer during the visit. Mandatory to wear a mask before entering CIC and through the period in CIC premises.
3. During the visit, the movement should be minimal with preventive measure: -
  - a. Assigned area based on purposes
  - b. Washroom
  - c. Collect/buy/eating a meal
4. The visitor should inform CIC counter staff if they have ordered meal delivery and advised to maintain the cleanliness of the workspace.
5. Any changes in the SOP will be following the national regulations and/or UMMC requirements.

Additional information:-

1. Execution of Clinical Trial Agreement (CTA) will proceed as usual. Wet-ink or e-signature from the sponsor is accepted.
2. New patient recruitment and Clinical trial patient follow up visits will proceed as usual. Patients need to apply for Visa to enter UMMC.
5. New study feasibility will proceed as usual.
6. On-site visit for Site selection visit (SSV) & Site initiation visit (SIV) is allowed. SSV and SIV also can be conducted virtually, CIC would suggest using a platform like ZOOM or Microsoft Team or Google meet.
7. On-site meeting for Prime site (IQVIA), Alliance site (Parexel), Strategic site (Novo Nordisk), Inspire site (Pfizer) and Novotech meeting are allowed. The meeting also can be conducted meeting virtually, CIC would suggest using a platform like ZOOM or Microsoft Team or Google meets.

Kindly take note that, Ms Juliana Wang Piek Lian retired from Clinical Investigation Centre, UMMC starting from 1st June 2020.

1. For matters regarding trial budget, please contact Miss Nurbazlin Musa (email: [nurbazlin@ummc.edu.my](mailto:nurbazlin@ummc.edu.my)),
2. For matters regarding archiving and invoice preparation for trials, please contact Madam Nurul Zfarina (email: [nurulzfarina.zaid@um.edu.my](mailto:nurulzfarina.zaid@um.edu.my)).

We shall send an update regularly.

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

Thank you.