Dear valued Sponsors and CRO,

Greetings from CIC.

COVID-19: Work from Home for Clinical Investigation Centre (CIC) Staff,

The Government has decided to implement the Movement Control Order extended, from April 14 to April 28, 2020, nationwide to curb the spread of the COVID-19 outbreak. This control order is made under the Prevention and Control of Infectious Diseases Act 1988 and the Police Act 1967. Top Management, University Malaya Medical Centre (UMMC) and University Malaya (UM) that the CIC staff shall be working from home starting from 14 April 2020 until 28 April 2020. Our operation hours are operating, as usual, that is from 8.30 am - 5.30 pm (Monday to Friday).

CIC staff will liaise with valued Sponsors and CRO via email for any matters as usual. Additionally information:-

- Execution of CTA - On hold
- New patient recruitment - On hold (except for difficult protocol)
- Clinical trial patient visit - proceed as usual
- New study feasibility - proceed as usual

UMMC-MREC Work Schedule & Format During MCO.

This is to inform you that UMMC-MREC is still operating despite the current COVID-19 situation. The study team will still be able to submit your application online accordingly and it will be reviewed by UMMC-MREC in a timely manner. However, in view of the current COVID-19-related restrictions, UMMC-MREC will be conducting its monthly meetings via Zoom, a conference call application. In addition, UMMC-MREC will implement a Primary Reviewer System that will minimise
the need for researchers to be present at the meeting. Hence, the Principal Investigator will be called to attend the Zoom meeting only when deemed necessary by the committee.

Establishment of COVID-19 Ethics Review Group (CERG)
UMMC-MREC has established the COVID-19 Ethics Review Group (CERG) to provide an independent review mechanism to facilitate expeditious ethical review of COVID-19 related research in this pandemic.

Herewith the composition of CERG and the flowchart for your information.


- Prof. Dr Ng Chirk Jenn, Department of Primary Care Medicine (Chair)
- Prof. Dr Sanjay Rampal Lekraj Rampal, Department of Social and Preventive Medicine
- Dr Nor Faizal bin Ahmad Bahuri, Department of Surgery
- Datin Assoc. Prof. Dr Grace Xavier, Faculty of Law (University of Malaya)
- Ms Wong Yin Yen, UMMC Department of Pharmacy

2. Workflow for COVID-19 Ethics Review

- The principal investigator submits COVID-19 related study application
- Head of Department (HOD) comments (max 3 days).
- Secretariat receives and vets application.
- CERG will meet once a week to review the applications and make recommendations.
- The decision will be made by the Chairman of UMMC-MREC.
- The Principal Investigators will be informed of the decision within two weeks after the UMMC-MREC secretariat has received the applications.

2. Flowchart of ethics review process for COVID-19 related research projects.

Workflow for COVID-19 Ethics Review Group

1. Principal investigator submits COVID-19 related study application.
2. HOD comments (max 3 days).
3. Secretariat receives and vets application.
4. Secretary informs Chair of CERG of new COVID-19 studies.
5. Secretary organises applications and related documents in OneDrive for CERG to review.
6. CERG will meet (once every week), review the applications and complete a Review Assessment Form (RAF) for each application (max 5 working days).
7. CERG informs Secretary that they have reviewed the applications.
8. Secretary informs Chair of MREC that the application is ready for classification.
9. Chair classifies application, based on the CERG’s comments and RAF, for expedited or full board review (max 2 working days).
   a. Expedited: Chair will approve the study, guided by CERG’s RAF and comments.
   b. Full Board: MREC will meet to provide a decision, guided by CERG’s RAF and comments.

We shall send an update regularly.
Please do not hesitate to contact us if there is any further query.

Thank you.

Warm regards,

Sender: Banusanthar

Clinical Investigation Centre
5th Floor, East Tower
University Malaya Medical Centre
59100 Kuala Lumpur.
Tel: +603-7949 2351 / +603-7949 2886
CIC Official Email: cic_staff@um.edu.my
Website: http://clinicalinvestigationcentre.com/
Find us on facebook: http://www.facebook.com/CLINICALINVESTIGATIONCENTRE

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