DRUG

NATIONAL AUTHORITY

Safe Drugs Save Lives

307/NDA/DPS/06/2020

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CIRCULAR NO. 038

Attention: Sponsors, Researchers, Research Ethics Committees.

Recommendations for resuming recruitment of participants by into authorized clinical trials

In line with section 40 of the National Drug Policy and Authority Act Cap 206, the National Drug Authority (NDA) authorizes drug-related clinical trials by issuing a clinical trial certificate.

As more information has become available regarding the evolution of the COVID-19 disease some of the restrictions following the Presidential directives have been lifted. The National Drug Authority hereby recommends the following for resuming the recruitment of **new participants** into clinical trials in the context of the on-going pandemic:

1. Research Institutions, Principal Investigators and Sponsors should submit a risk mitigation plan for participant recruitment which should be in line with the Ministry of Health guidelines and among other considerations should include measures that ensure identification and isolation of individuals suspected to have COVID-19 disease, social distancing and use of appropriate personal protective equipment to ensure safety of the participants as well as the trial personnel.

2. Every effort should be made to ensure that collection of end point data is not compromised. Where trial procedures as detailed in the approved protocol are not followed, such deviations should be documented and all relevant authorities notified accordingly. The Sponsor and Principal Investigator should assess and document the impact of such deviations on the data integrity and scientific conclusions on the study.

The National Drug Authority will review the risk mitigation plans for participant recruitment, provide a response and where applicable make additional recommendations.

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