INSTITUTIONAL REVIEW BOARD
Government College University, Faisalabad

Study No: 19871 IRB No: 871

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Ref. No.: GCUF/ERC/ 2271 Dated: 25-06-21

CERTIFICATE OF APPROVAL

Members of the Institutional Review Board, Government College University Faisalabad, have evaluated the synopsis of a study titled "Comparative assessment of anti-diabetic efficacy of metformin plus dapafligozin with metformin plus insulin- sensitizer or secretagogues in patients with diabetes mellitus type-2 in Pakistan: A randomized trial" submitted by Mr. Muhammad Irfan Sohail Khan (Principal Investigator) being supervised by Dr. Malik Hassan Mehmood (Chairperson, Department of Pharmacology, Government College University Faisalabad). The synopsis and study to be conducted is for the completion of M.Phil Pharmacology as per requirements and rules. The said study shall be conducted in Mian Trust Hospital, Faisalabad.

The committee members had studied thoroughly the planned methodology, ethical considerations, data acquisition and analysis procedures.

Therefore committee believes that the study planned is in full compliance with national and international regulatory rules and ethical considerations. Further, the committee believes that the Human subjects are not likely to face any type of serious adverse events and the health will remain safe during the course of study and after the study, there will be no long term harmful effects of this study.

Therefore, the study is certified, registered and approved for a period of 1 year. This ethical approval certificate is being issued without any obligation for registration of study in World Health Organization's recognized Clinical Trial Registry.

The Principal Investigator must register the study in a Clinical Trial Registry. Further, Principal Investigator must also take ethical approval from the concerned setting where the trial is to be conducted. If any change is necessary to be made in the protocols of study or any extension in the period of the study is required, it should be notified to the Institutional Review Board for approval.

23/06/2021

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(Approved by the Board of Revenue Govt. Of Pakistan under section 2(36) of Income Tax Ordinance 2001 read with rule 214 of Income Tax Rules 2002)

MIAN MUHAMMAD TRUST HOSPITAL

(Founder: Late Al-Haj Sheikh Mian Muhammad)

Date: 30 June 2021

Ref #: MMTH/4878

CERTIFICATE OF APPROVAL

Members of the Ethical Review Committee (ERC), Mian Trust hospital Faisalabad, have evaluated the synopsis of a study titled "Comparative assessment of anti-diabetic efficacy of metformin plus dapafligozin with metformin plus insulin- sensitizer or secretagogues in patients with diabetes mellitus type-2 in Pakistan: A randomized trial" submitted by Mr. Muhammad Irfan Sohail Khan (Principal Investigator) being supervised by Dr. Malik Hassan Mehmood (Chairperson, Department of Pharmacology, Government College University Faisalabad). The said study shall be conducted in Mian Trust Hospital, Faisalabad. Principal Investigator has been granted approval by his university to conduct study.

The committee members had studied thoroughly the planned methodology, ethical considerations, data acquisition and analysis procedures.

Therefore, committee believes that the study planned is in full compliance with national and international regulatory rules and ethical considerations. Further, the committee believes that the Human subjects are not likely to face any type of serious adverse events and the health will remain safe during the course of study and after the study, there will be no long-term harmful effects of this study.

Therefore, the study is certified, registered and approved for a period of 1 year. This ethical approval certificate is being issued without any obligation for registration of study in World Health Organization's recognized Clinical Trial Registry. The study must be started and conducted after registration of study by Clinical Trial Registry, and data sharing statement from clinical trial registry should be submitted to ERC of this hospital.

If any change is necessary to be made in the protocols of study or any extension in the period of the study is required, it should be notified to the Institutional Review Board for approval.

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