



لجنة أخلاقيات البحث العلمي

Serial: 1 - 2018

22st of October 2018

Dear Principal Investigator, Dr. Osama Mohamed Osama Hegazy

This is to certify that the Research Ethics Committee (REC) for Human Subject Research at the Faculty of Medicine, Helwan University, Cairo, Egypt, has approved your research protocol entitled: *'Effect of direct acting antivirals on extrahepatic cutaneous manifestations of chronic hepatitis C virus'*.

Approval was liberated after revision of the submitted study file, including:

1. Protocol
2. Informed consent, Arabic version
3. Application form for human research
4. CVs of all investigators

Type of review: Full board on 14 October 2018

Approval validity: from 22/10/2018 to 22/10/2019

The research should not continue after the approval period without further REC review and renewal of approval and only approved informed-consent forms must be used. The principle investigator has to report to the REC any of the following for approval or acknowledgment: any protocol deviation or violation, any protocol amendment prior to its conduction, and study closure/termination reports are required. Also, safety letters every 6 months, and reports about suspected unexpected serious adverse events (SUSAR) within 48 hours when requested. It is the responsibility of the principal investigator and the study team to safeguard the rights and welfare of human subjects involved in research.

N.B. FMHU-REC approval does not include official approval for study-site conduction, which you should get before study initiation.

FMHU-REC is organized and operated according to the Declaration of Helsinki.

Sincerely,

Dr.

FMHU-REC Chair

