

**Zagazig University** Faculty of Medicine Institutional Review Board (IRB)

نموذج ۸

ZU-IRB #9841/25-9-2020

## NOTICE OF APPROVAL

IRB#:9841-25-9-2020

Approval DATE: 25-9-2020

Principal Investigator (PI): Tamer.A.A.M.Habeeb

Title of Protocol:

Hepatobiliary Manifestations following Two-Stages Elective Laparoscopic Restorative Proctocolectomy for Patients with Ulcerative Colitis. A prospective Observational Study.

Dear Dr: Tamer.A.A.M.Habeeb

e-mail: IRB\_123@medicine.zu.edu.eg

The IRB has reviewed and assessed the above named study regarding the potential risks and benefits based on the Declaration of Helsinki. The "ratio" of risk to benefit is reasonable, given the goals of the study. The variables assessed, including the proposed subject populations, proposed procedures and scientific background are supporting the study. The IRB approved that it is within the ethical guidelines as outlined in the Declaration of Helsinki.

Having met the requirements set forth by the Institutional Review Board by an expedited review process

If, during the course of the research, there are any serious adverse events, ,confidentiality concerns, these should be brought to the immediate attention of the IRB.

You should not initiate changes in the approved research protocol without IRB review and approval "except if found necessary to eliminate immediate hazards to the human subjects".

> Sincerely CHair IRB 5 man Abdell

و حدة المراجعة المؤسسية للبحث العلمي ( IRB)