



IRB NO: 00007555-FWA NO: 00015712

<http://www.hhs.gov/ohrp/assurances/index.html>

### Ethics Committee Board Decision

The ethics committee of the Faculty of Medicine – Alexandria University is constituted and operates according to ICH GCP guidelines and applicable local and Institutional regulations and guidelines which govern IRB operation. The committee met on 16/03/2017 and reviewed the presented documents for the following protocol.

#### Master Study Title

**Efficacy And Safety Of Gratsivir (Sofobuvir)- Daclatasvir Dual Therapy in Egyptian Adolescent Patients with Chronic Hepatitis C Infection"**

**A prospective, randomized, multi-center study**

#### Short title

**Sofosbuvir Based Therapy In Pediatric HCV**

**Protocol no :- Sofo -03**

**Version and data:- 1/2/2016**

#### The Sponsor

**Faculty of Medicine, Alexandria University & University of Alabama at Birmingham**

#### IRB Members

**A**

1	Prof. Dr. Maha Ghanem,	Prof of Forensic Medicine & Toxicology.	Chairman
2	Prof. Dr. Amal Mashaly	Prof of Forensic Medicine & Toxicology.	Member
3	Prof. Dr. Mohamed Rafeek Khalil,	Prof of Surgery,	Member
4	Prof. Dr. Mohamed tharwat Ghoniem,	Prof of Pharmacology ,	Member
5	Prof. Dr. Laila Abdou,	Prof of Pathology,	Member
6	Prof. Dr. Sohair Saied,	Prof of Int. Medicine,	Member
7	Prof. Dr. Ahmed Abd – El Aziz,	Prof of Gynecology& Obstetrics,	Member
8	Prof. Dr. Ahmed Elattar,	Prof of Anesthesia& Critical care,	Member
9	Prof. Dr. Ayman Yousef,	Prof of Neurology& Psychiatry,	Member
10	Prof. Dr. Mervat El-Azouny,	Prof of Parasitological,	Member
11	Prof. Dr. Dalal Elkaffash	Prof of Clinical Pathology,	Member
12	Prof. Dr. Nadia Fargali,	Prof of Public Health,	Member
13	Prof. Dr. Safaa Elshanawany,	Prof of Forensic Medicine& Toxicology.	Administrator
14	.Prof. DR. Heba Kassem,	Assistant Prof. of Pathology,	Member
15	Prof. Dr. Mohamed Salem,	Prof of Faculty of Fine Arts,	Member





ETHICS COMMITTEE  
FACULTY OF MEDICINE  
ALEXANDRIA UNIVERSITY

Documents Presented	version	Date	Language
The protocol.	02	01 2/12/2016	English
Informed consent Arabic	-	01 2/12/2016	Arabic
Informed consent English	-	01 2/12/2016	English
Final Decision			
<input checked="" type="checkbox"/> Approved		<input type="checkbox"/> Approved to be continued.	
<input type="checkbox"/> Approved with recommendation		<input type="checkbox"/> Tabled.	
<input type="checkbox"/> Approved with stipulation		<input type="checkbox"/> Disapproved.	

Prof. Dr. Maha Ghanem  
Chairman of Ethics Committee

Issue Date: 16 / 3 / 2017

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