



Dr. David
Sayed

Institutional Review Board Decision

The Institution Review Board of the National Cancer Institute 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 22/07/2008 and reviewed the presented documents for the following protocol

Master Study Title	
Biomarkers of HCV infection-associated HCC	
Version and Date of Protocol	
Documents presented	
<input checked="" type="checkbox"/> Protocol <input type="checkbox"/> Amendment <input type="checkbox"/> Protocol Signature Page <input checked="" type="checkbox"/> Patient Information and Informed Consent in English	<input checked="" type="checkbox"/> Arabic translation of Patient Information and Informed Consent <input type="checkbox"/> CRFs <input checked="" type="checkbox"/> Investigator CV
<input type="checkbox"/> The principal investigator is a member of IRB but didn't participate in voting for the approval of the protocol	
Recommendations	
<input checked="" type="checkbox"/> Approval <input type="checkbox"/> Modification required	<input type="checkbox"/> Disapproval <input type="checkbox"/> Termination or suspension of any prior approval
The IRB approved the principal investigator Prof. Abdel Rahman Zekri to conduct this trial at the National Cancer Institute. She has to report any SAE during trial conduction to the IRB within 24 hrs of notification of such an event in addition to presentation of six (6) monthly Progress Reports to IRB and receive the safety letters on regular basis every three (3) months	
Final Decision	
<input checked="" type="checkbox"/> Approved <input type="checkbox"/> Approved with recommendation <input type="checkbox"/> Approved with stipulation	<input type="checkbox"/> Approved to be continued <input type="checkbox"/> Tabled <input type="checkbox"/> Disapproved <input type="checkbox"/> Study Termination

Signature
NCI-IRB Chairman

Issue Date: 27th Jul 2008
IRB Stamp

Prof. Salah Abdel Hady

Cairo University
National Cancer Institute
IRB
Institutional Review Board