Hartford HealthCare

HUMAN RESEARCH PROTECTION PROGRAM
80 SEYMOUR STREET
P.O. BOX 5037
HARTFORD, CT. 06102-5037
860/972-2893 FAX 860/545-5112
irb@hhchealth.org

April 22, 2019

Dr. Saverio Ligato, MD
c/o Ayesha Siddique

Institutional Review Board (IRB) - (Assurance #FWA00021932) IRB-Panel_A

Study Title: Copy of Drug and herbal/dietary supplements -induced liver injury: a five year experience in a tertiary care center
IRB #: HHC-2019-0045

Status: Approved
Approval Date: 04/22/2019
Approval Valid Through: 04/21/2020

Type of Review: Expedite
Category (if applicable): Category 5: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis)

Approved Key Study Personnel: Ligato, Saverio, MD; Siddique, Ayesha

This approval includes the following materials:

Submission Components Approved		
Document Type	Version	Date Approved
Submission-Initial Review Submission Form	Version 1.1	
Document-protocol	Version 1.0	04/22/2019

Informed Consent:
If your project requires the use of a written informed consent document, the version of the consent which has been approved for use by the IRB is available within the iRIS system. You must use this stamped form to enroll participants until the project is completed, another extension is approved, or an approved revision supersedes this version.

Progress Reports:
This project requires continued review and approval by the IRB prior to the expiration date. You will be expected to submit the first Progress Report on: **02/22/2020**. The approval of the project will be considered "Lapsed" if a "*Request for Continuation (Progress Report)*" Form has not been approved prior to that expiration date. A lapse of IRB approval means that no work with human subjects may be conducted, including enrollment of new subjects, data analysis, etc. until re-approval has been granted.

The "*Request for Continuation (Progress Report)*" Form must include the number of subjects enrolled since the previous report or initiation of the study, as well as a copy of signature page of the informed consent for all subjects enrolled during the approval period.

Please be aware that you will be expected to provide the composition of the patients enrolled by number of males/females and minorities (Hispanic, Black, Other). You should ensure you have procedures in place to collect and track this information.

Protocol and Consent Changes:
You are expected to inform the IRB of proposed protocol or informed consent changes. Any such change must be approved by the IRB *prior to implementation*, except in cases of emergency, when prearranged with the chairman or his designee. To do so, submit the revised materials using the "*IRB Request for Modification/Amendment"* Form.

Unanticipated Problems/Adverse Events:
You must also notify the IRB promptly of any events that are:

- *Unexpected* (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- *Related or possibly related* to the procedures involved in the research; **and**
- *Suggests that the research places subjects or others at a greater risk of harm* (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.

These should be reported by submitting the "*IRB Unanticipated Event/Problem Report Form*."

Beginning the Research:
Please be aware that before implementation of this study, you must have Grants & Contracts approval of your budget, in-kind budget, clinical study agreement, contract, etc. as applicable.

Responsibilities:
As the principal investigator (PI), you are responsible for personally conducting or supervising the conduct of human subjects research and for protecting the rights, safety, and welfare of the subjects enrolled in the research. You are expected to ensure your research is conducted in an ethical manner and in accordance with all federal, state, and local laws and regulations, institutional and HRPP policies, and requirements or determinations of the IRB.

The Hartford HealthCare HRPP Policies and Procedures and the Belmont Report are available for your review on our website at: https://hartfordhealthcare.org/health-professionals/research/medical-professionals/institutional-review-board-irb/policies .

Sincerely,

Signature applied by James Rancourt on 04/22/2019 01:12:47 PM EDT

James Rancourt, PharmD
Institutional Review Board - IRB-Panel_A
Designated Reviewer