University of Nebraska Medical Center

NEBRASKA'S HEALTH SCIENCE CENTER
A Partner with Nebraska Medical Center

CENTER FOR CLINICAL AND TRANSLATIONAL RESEARCH

September 22, 2010

Yazen Alnouti, Ph.D.
College of Pharmacy
UNMC 6025

Re: IRB#: Pending "Sulfation of Bile Acids as a Biomarker for Hepatobiliary Diseases

Dear Dr. Alnouti:

I am pleased to inform you that the Pilot Grant Review Committee of the Clinical Research Center has approved your above referenced proposal for use of the CRC space and coordinators. Your company center is #MXH/99-925-1374. The approved budget for $180,948.00 is enclosed. This does not include costs for meals. You will not be able to start enrolling until we have a copy of the IRB approval letter. Please call LuAnn Larson RN, BSN @ 9-8555 in the CRC to set up a time to review your protocol with the staff.

It should be noted that the Pilot Grant Review Committee, in light of the recommendations regarding the registering of studies with clincaltrials.gov, require registering all required studies on the clinicaltrials.gov website. For information on how to register your study you may go to the CRC website www.clinicalresearch.unmc.edu and click on the link to Internal Resources.

It is now a policy that all investigators and co-investigators receiving support for the Center for Clinical and Translational Research (CCTR) complete the research interest check list on the ADIS (https://edge.unmc.edu/adis/index.asp?bw=p) website. Please verify that the primary investigator and all co-investigators have completed this checklist. If there are questions please contact Tara Stafford at 9-6803 or tstafford@unmc.edu for assistance. You will also need to log your study into the Clinical Trials Database found on the RSS website. If you are unfamiliar with this site instructions can be obtained from LuAnn Larson, llarson@unmc.edu.

Please be advised that as part of the CRC policy, any protocol can be selected for RSA review of consent process which would include direct observation of the consent process. The Research Subject Advocate has an active role in the CRC assuring that our participants are assured of an informed consent and can verbalize their confidence in the fact that they understand all that will be expected of them and the risks and benefits associated with their participation.

We will contact you annually to obtain an update to include changes in the IRB status or past or anticipated adverse events, anticipated future visits, and any abstracts, manuscripts or grants submitted or funded from this work.

Please forward all IRB correspondence that indicates a change in status of your protocol and all unexpected adverse event reports to the Clinical Research Center when or if they occur.

The following information is essential for accurate accounting of the services/tests for each patient enrolled in a research project. Since you are responsible for the billing to this account, please read the following instructions carefully.

1. A Grant Account must be established in Centricity for each patient that you enroll in your study. Grant demographics should be updated every visit.

2. All charges that are to be charged to the research grant as primary should be designated as such at the time of ordering. The patient or appropriate insurance will be responsible for whatever office visit charge is negotiated with the clinic or other site where the patient is seen.

3. The Primary Investigator is responsible for accurate billing of items to both the RSF grant account as well as clinical care to insurance. It is essential that the PI orients anyone who will be performing research billing on how to do this accurately. If you are not familiar with that process it is suggested the appropriate person get training from the Clinical Research Center staff. Call 9-7685 for assistance.

4. When the patient completes the study, enter an "end date" for the "Grant Account" in Centricity. This can be done when the account is opened as well.

****NOTE****

Research Support Fund Primary - The procedures are strictly research procedures/tests and are billed to the grant only. These tests are designated on the approved budget. Also, when entering a charge in the system, be sure to probe the exact procedure code that is on the approved budget.

Research Support Fund Secondary - The standard patient care procedures and/or tests are billed to all insurance listed and to the grant last. The grant will then pick up anything that has been billed to insurance and rejected. This should only be used in special circumstances.

If you have any concerns, please contact Bev Shaver, Research Billing Specialist, at x9-8205, she will assist you with grant demographics in Centricity.

Please be reminded that to the extent that hospital charges are written off for patients participating in clinical research, professional fees and clinic visits cannot be written off. In-patient charges cannot be billed to the grant and must be moved by Bev. You must contact her directly with that information. In addition, please note that you are responsible for submitting yearly progress reports and current IRB approval to this committee.

Please cite the UNMC Research Support Fund in all publications resulting from work utilizing these resources. A statement such as *"This work was supported by a Research Support Fund grant from the Nebraska Medical Center and the University of Nebraska Medical Center"* would be appropriate. Forward copies of any publications resulting from your research to the Clinical Research Center. Publications are used as a measure of productivity and thus translate into budget dollars and will be evaluated when future funding is sought.

Good luck with your investigation.

Sincerely,

William J. Burke, M.D.
Chair, Clinical Advisory Committee
Clinical Research Center

Project Title: Sulfation of Bile Acids as a Biomarker for Hepatobiliary Diseases

Project Investigator: Yazen Alnouti, PhD

Department: College of Pharmacy

Please provide below: the revenue center, procedure code, procedure description, and the quantity of procedures that will be incurred for the duration of the study. Be sure to include all supplies that are needed to carry out any procedures you may have listed. Put an "X" in the Standard Patient Care box if the test(s) are such that can be billed third party initially.

If you have any questions, please feel free to contact LuAnn Larson at ext. 98555. Thank-you. **9/23/2010**

Budget is for 200 patients

REVENUE CENTER	PROCEDURE CODE	PROCEDURE DESCRIPTION	QUANTITY	HOSPITAL CHARGE/ UNIT	TOTAL HOSPITAL CHARGE
554	84448	ALT Serum Levels	800	$27.64	$22,112.00
554	84450	AST Serum Levels	800	$27.64	$22,112.00
554	82977	GGT Serum Levels	800	$38.73	$30,984.00
554	85610	Pro Time (INR)	800	$37.00	$29,600.00
554	82040	Albumin	1000	$28.63	$28,630.00
554	82562	Creatinine	1000	$28.63	$28,630.00
580	OOO42	CRC Visit New / Level 2	200	$54.40	$10,880.00
580	OOO84	CRC Urine Collection	800	$10.00	$8,000.00
				TOTAL:	180,948.00