University of California Los Angeles
11000 Kinross Avenue, Suite 211
Los Angeles, CA 90095-1694

http://ohrpp.research.ucla.edu
GC-IRB: (310) 825-7122
M-IRB: (310) 825-5344

APPROVAL NOTICE
New Study

DATE:	1/26/2016
TO:	ZUOFENG ZHANG EPIDEMIOLOGY
FROM:	ALISON MOORE, MPH, MD Chair, SGIRB
RE:	IRB#15-001883 Risk factors for liver disease among adults of Mexican descent in the United States and Mexico: a comparative study

The UCLA Institutional Review Board (UCLA IRB) has approved the above-referenced study. UCLA's Federalwide Assurance (FWA) with Department of Health and Human Services is FWA00004642.

Submission and Review Information

Type of Review	Expedited Review
Approval Date	1/25/2016
Expiration Date of the Study	1/24/2017
Funding Source(s)	1) PROGRAMA DE INVESTIGACION EN MIGRACION Y SALUD *Grant PI*: ZUOFENG ZHANG *Grant Title*: Risk factors for liver disease among adults of Mexican descent in the United States and Mexico: a comparative study

Regulatory Determinations

-- **Expedited Review Category(ies)** - The UCLA IRB determined that the research meets the requirements for expedited review per 45 CFR 46.110 category 5.

-- **Waiver of Informed Consent** - The UCLA IRB waived the requirement for informed consent under 45 CFR 46.116(d) for the entire study.

Important Note: Approval by the Institutional Review Board does not, in and of itself, constitute approval for the implementation of this research. Other UCLA clearances and approvals or other external agency or collaborating institutional approvals may be required before study activities are initiated. Research undertaken in conjunction with outside entities, such as drug or device companies, are typically contractual in nature and require an agreement between the University and the entity.

General Conditions of Approval
As indicated in the PI Assurances as part of the IRB requirements for approval, the PI has ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the IRB.

The PI and study team will comply with all UCLA policies and procedures, as well as with all applicable Federal, State, and local laws regarding the protection of human subjects in research, including, but not limited to, the following:

- Ensuring that the personnel performing the project are qualified, appropriately trained, and will adhere to the provisions of the approved protocol,
- Implementing no changes in the approved protocol or consent process or documents without prior IRB approval (except in an emergency, if necessary to safeguard the well-being of human subjects and then notifying the IRB as soon as possible afterwards),
- Obtaining the legally effective informed consent from human subjects of their legally responsible representative, and using only the currently approved consent process and stamped consent documents, as appropriate, with human subjects,
- Reporting serious or unexpected adverse events as well as protocol violations or other incidents related to the protocol to the IRB according to the OHRPP reporting requirements.
- Assuring that adequate resources to protect research participants (i.e., personnel, funding, time, equipment and space) are in place before implementing the research project, and that the research will stop if adequate resources become unavailable.
- Arranging for a co-investigator to assume direct responsibility of the study if the PI will be unavailable to direct this research personally, for example, when on sabbatical leave or vacation or other absences. Either this person is named as co-investigator in this application, or advising IRB via webIRB in advance of such arrangements.

University of California Los Angeles
10889 Wilshire Blvd, Suite 830
Los Angeles, CA 90095-1406

http://ora.research.ucla.edu/ohrpp
General Campus IRB: (310) 825-7122
Medical IRB: (310) 825-5344

APPROVAL NOTICE

DATE:	1/20/2017
TO:	ZUOFENG ZHANG, MD, PhD CANCER PREVENTION & CNTRL RESEARCH
FROM:	THOMAS COATES, PhD Chair, SGIRB
RE:	IRB#15-001883-CR-00001 2017 Review for IRB#15-001883 Risk factors for liver disease among adults of Mexican descent in the United States and Mexico: a comparative study

The UCLA Institutional Review Board (UCLA IRB) has approved the submission listed below. UCLA's Federalwide Assurance (FWA) with Department of Health and Human Services is FWA00004642.

Submission and Review Information

Type of Submission	Continuing Review
Type of Review	Expedited Review
Approval Date for this Submission	1/19/2017
Expiration Date of the Study	1/18/2020
Funding Source(s)	1) PROGRAMA DE INVESTIGACION EN MIGRACION Y SALUD *Grant PI*: ZUOFENG ZHANG *Grant Title*: Risk factors for liver disease among adults of Mexican descent in the United States and Mexico: a comparative study
Initial IRB Approval Type & Date for this Study	IRB Review: Expedited

Specific Conditions for Approval

-- **Data Analysis Only** - the remaining research activities are limited to data analysis. No additional data may be collected.

Regulatory Determinations

-- **Expedited Review Category(ies)** - The UCLA IRB determined that the research meets the requirements for expedited review per 45 CFR 46.110 category 5.

-- The IRB has determined that this study meets the criteria for a 3 year extended approval. (For reference, please see the OHRPP guidance document "Extended Approval for Minimal Risk Research Not Subject to Federal Oversight" at http://ora.research.ucla.edu/OHRPP/Documents/Policy/4/Extended_Approval.pdf)

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MÉXICO

Dirección de Prestaciones Médicas
Unidad de Educación, Investigación y Políticas de Salud
Coordinación de Investigación en Salud

IMSS

"2015, Año del Generalísimo José María Morelos y Pavón".

28 de abril del 2015

Ref. 09-B5-61-2800/201500/ 1266

Dr. Flores Leonard Ivonne Nicole
Unidad de Investigación Epidemiológica y en Servicios de Salud Morelos
Morelos

Presente:

Informo a usted que el protocolo titulado: **FACTORES DE RIESGO DE ENFERMEDAD HEPÁTICA EN ADULTOS MEXICANOS EN LOS ESTADOS UNIDOS Y MEXICO: UN ESTUDIO COMPARATIVO** , fue sometido a la consideración de esta Comisión Nacional de Investigación Científica.

Los procedimientos propuestos en el protocolo cumplen con los requerimientos de las normas vigentes, con base en las opiniones de los vocales de la Comisión de Ética y Científica, se ha emitido el dictamen de **AUTORIZADO**, con número de registro: R-2015-785-034.

De acuerdo a la normatividad vigente, deberá informar a esta Comisión en los meses de enero y julio de cada año, acerca del desarrollo del proyecto a su cargo. Este dictamen sólo tiene vigencia de un año. Por lo que en caso de ser necesario requerirá solicitar una reaprobación a la Comisión de Ética en Investigación de la Comisión Nacional de Investigación Científica, al término de la vigencia del mismo.

Atentamente,

Dr. Fabio Salamanca Gómez
Presidente
Comisión Nacional de Investigación Científica

Anexo comentarios:

JAMA/ iah. F-CNIC-2015-52

INSTITUTO MEXICANO DEL SEGURO SOCIAL
DIRECCIÓN DE PRESTACIONES MÉDICAS
UNIDAD DE EDUCACIÓN, INVESTIGACIÓN Y POLÍTICAS DE SALUD
COORDINACIÓN DE INVESTIGACIÓN EN SALUD

COMISIÓN NACIONAL DE INVESTIGACIÓN CIENTÍFICA

Ref. 09-B5-61-2800/***732***

Marzo 16, 2005

DOCTOR JORGE SALMERÓN CASTRO
Jefe de la Unidad de Investigación Epidemiológica y en Servicios de Salud
Delegación Morelos

Informo a usted que el proyecto titulado: **"Cohorte de trabajadores del IMSS Morelos"**, fue sometido a la consideración de esta Comisión Nacional de Investigación Científica.

Los procedimientos propuestos en el protocolo cumplen con los requerimientos de las normas éticas vigentes y la carta de consentimiento informado es suficientemente explícita, por lo cual tengo el agrado de hacerle saber que con base en las opiniones de los vocales de esta Comisión, se ha emitido dictamen de **AUTORIZADO**, con número de registro: **2005-785-012.**

De acuerdo a la normatividad institucional vigente, deberá informar semestralmente a esta Comisión, acerca del desarrollo del proyecto a su cargo.

Atentamente

DOCTOR ALEJANDRO GÓMEZ DELGADO
Secretario Ejecutivo
Comisión Nacional de Investigación Científica

AGD'brs