UF Institutional Review Board
UNIVERSITY of FLORIDA

Health Center Institutional Review Board
FWA00005790

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DATE: 7/14/2020
TO: Roniel Cabrera
1600 SW Archer Road M440
Gainesville, Florida 32610
FROM: Peter Iafrate, IRB Chairman, University of Florida
Chair IRB-01
IRB#: **Continuing Review for IRB201701953**
TITLE: Retrospective Chronic Liver Disease: Natural history of chronic liver disease, prognostic factors, therapy modalities, complications and survival outcomes.

Approved as Expedited: Continuing Review	**Expires on: 7/10/2023**

*****Please review this Institutional Guideline to determine if you can, in fact, continue your activities and/or enroll participants:**
https://clinicalresearch.ctsi.ufl.edu/covid-19/resuming-hsr-study-activities/***

On 7/10/2020, the IRB re-approved you to continue conducting the above-listed research project. You are approved to enroll 10000 subjects. This study is approved as expedited because it poses minimal risk and is approved under the following expedited category:

> 5. Research involving materials (data, documents, records or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis). Note: Some research in this category may be exempt from the regulations for the protection of human subjects as noted in 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.

Approval Includes:

Consent Waiver Type:
Full Waiver of Informed Consent
Subjects will not be informed nor will consent be sought or obtained prior to their involvement in the research (including collection of data from identifiable records or tissue)

HIPAA Waiver Type:

to enroll subjects in the study

Principal Investigator Responsibilities:

The PI is responsible for the conduct of the study. Please review these responsibilities described at: http://irb.ufl.edu/irb01/researcher-information/researcherresponsibilities.html
Important responsibilities described at the above link include:

- Using currently approved consent form to enroll subjects (if applicable)
- Renewing your study before expiration
- Obtaining approval for revisions before implementation
- Reporting Adverse Events
- Retention of Research Records
- Obtaining approval to conduct research at the VA
- Notifying other parties about this project's approval status

Study Team:

Consuelo	Soldevila-Pico	Co-Investigator
Chelsea	Jacobs	Co-Investigator
David	Nelson	Co-Investigator
Virginia	Clark	Co-Investigator
April	Goddard	Study Coordinator
Edward	De Leo	Co-Investigator
Ahmed	Ouni	Co-Investigator
Robert	Case	Co-Investigator
Lindsey	Woody	Co-Investigator
Andreas	Zori	Co-Investigator
Tiffany	Harrison	Study Coordinator
Wissam	Hanayneh	Co-Investigator
Eduardo	Milla	Co-Investigator
Media	Ismael	Co-Investigator
Giuseppe	Morelli	Co-Investigator
Amitabh	Suman	Co-Investigator
Kelsey	Pan	Co-Investigator
Roberto	Firpi-Morell	Co-Investigator