UF | Institutional Review Board
UNIVERSITY of FLORIDA

Health Center Institutional Review Board
FWA00005790

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DATE: 4/1/2016

TO: Jorge Lascano
1600 sw archer road M452
Gainesville , Florida 32610

FROM: Peter Iafrate, Pharm.D
Chair IRB-01

IRB#: **IRB201500737**

TITLE: Prognostic markers for the development of Cystic Fibrosis related Liver Disease.

Approved as Expedited	**Expires on: 3/31/2019** **Discretionary Policy in Effect**

You have received IRB approval to conduct the above-listed research project. Approval of this project was granted on 3/31/2016 by IRB-01 . This study is approved as expedited because it poses minimal risk and is approved under the following expedited category/categories:

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). [Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. (45 CFR 46.101[b][4].) This listing refers only to research that is not exempt.]

Approval Includes, but is not limited to:

Consent Waiver Type(s):

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(s): 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:

Richard Helton Co-Investigator

The Foundation for The Gator Nation

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