THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

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To: A Barritt
Medicine-Gastroenterology

From: Office of Human Research Ethics

Date: 3/24/2020
RE: Determination that Research or Research-Like Activity does not require IRB Approval
Study #: 20-0794

Study Title: Surveillance Epidemiology of Coronavirus (COVID 19) Under Research Exclusion in Cirrhosis (SECURE-CIRRHOSIS)

This submission, Reference ID 278998, was reviewed by the Office of Human Research Ethics, which has determined that this submission does not constitute human subjects research as defined under federal regulations [45 CFR 46.102 (e or l) and 21 CFR 56.102(c)(e)(l)] and does not require IRB approval.

Study Description:
Purpose: To create a de-identified registry of cases of Novel Coronavirus (COVID 19) among individuals with chronic liver diseases (both pre- and post-transplant) to study effects of COVID 19 in these populations.

Procedures (methods): We will establish a web-based platform to allow physician or other healthcare provider self-report of cases of confirmed COVID 19 in individuals with chronic liver diseases or post-liver transplantation. The web-based platform will link to a secure database where providers can report details of cases. The case report form will include items requesting the following information: age, country of residence, state of residence (if applicable), year of COVID-19 diagnosis, name of center/practice/physician providing care, gender, race, ethnicity, patient's etiology of liver disease, immunosuppressive medications at time of diagnosis, severity/complications of liver disease, whether the patient died of COVID 19, whether the patient was hospitalized (if hospitalized, name of hospital, length of stay, and complications during hospitalization).

The web-based registry will be added to on a volunteer basis. Advertisement for the registry will be accomplished through adult and pediatric gastroenterology and hepatology professional societies (including the American Association for the Study of Liver Diseases, European Association for the Study of the Liver, British Association for the Study of the Liver, Asian Pacific Association for the Study of the Liver, American College of Gastroenterology and the American Gastroenterological Association), professional listservs, word-of-mouth, and other marketing platforms. The information captured in the database will be used to track the epidemiology of COVID-19 among individuals with cirrhosis and individuals who are post-liver transplantation and to evaluate for potential associations between COVID 19 prevalence
and severity (as measured by death and/or hospitalization) and demographic or medical factors. Once

a respondent completes a survey they will not be able to access the survey again or update it.

We will submit a separate IRB application for a human subject research activity for the inclusion of data from UNC patients to this registry.

Summary of changes approved with this submission:

We have made small alterations to the data submission form. None of the additional questions include potentially identifiable information. The additional questions include:

- Complications of liver disease prior to COVID infection

- Laboratory data prior to COVID infection

- Types of immunosuppression medications used at time of COVID infection

- Cause of death

A full list of the questions included are attached to this application.

Please be aware that approval may still be required from other relevant authorities or "gatekeepers" (e.g., school principals, facility directors, custodians of records), even though IRB approval is not required.

If your study protocol changes in such a way that this determination will no longer apply, you should contact the above IRB before making the changes.

CC:
Erica Brenner, Epidemiology
Theodore James, Medicine-Gastroenterology
Michael Kappelman, Pediatrics - Gastroenterology
Andrew Moon, Medicine-Gastroenterology