

IRB Notice - 20-0737

IRB <no_reply@unc.edu>

Wed 3/11/2020 10:36 AM

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To: Erica Brenner and Michael Kappelman
Epidemiology

From: Office of Human Research Ethics

Date: 3/11/2020

RE: Determination that Research or Research-Like Activity does not require IRB Approval

Study #: 20-0737

Study Title: Surveillance Epidemiology of Coronavirus (COVID 19) Under Research Exclusion (SECURE)

This submission, Reference ID 278066, 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 inflammatory bowel disease (IBD) and other patient populations treated with immune suppression 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 IBD. 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), first three digits of zip code, year of COVID 19 diagnosis, name of center/practice/physician providing care (will remove if this precludes NHSR determination), gender, race, ethnicity, patient's diagnosis, immunosuppressive medications at time of diagnosis, whether the patient died of COVID 19, whether the patient was hospitalized (if hospitalized, name of hospital, length of stay, and need for a ventilator). No information that could identify the patient specifically will be requested.

The web-based registry will be added to on a volunteer basis. Advertisement for the registry will be accomplished through adult and pediatric gastroenterology professional societies (including Improve Care Now, the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition, 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 IBD and other conditions treated with immune suppressive medications 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.

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.

Lori Slack , Pediatrics

Stephanie Davis , Pediatrics - Pulmonology

Til Stürmer , Epidemiology|RB Informational Message - please do not use email REPLY to this address