

Research Institute

1001 University Place
Evanston, Illinois 60201
www.northshore.org
Phone (224) 364-7100
Fax (847) 570-8011

May 20, 2022

Liana Billings, M.D., MMSc
Department of Medicine/Endocrinology
NorthShore University HealthSystem
9977 Woods Drive
Skokie, IL 60076

Re: EH20-060: Billings, Liana M.D., MMSc: A Longitudinal Observational Study of Patients with Nonalcoholic Steatohepatitis (NASH) and Related Conditions Across the Entire Spectrum of Nonalcoholic Fatty Liver Disease (NAFLD)
Protocol Version Amendment 3 dated August 19, 2021

Study Revision 3 dated May 5, 2022. Consent Modification

Dear Dr. Billings:

The Research Institute received your request for a revision of the above-referenced research study on 5/6/2022. The revision has been reviewed in the Research Institute and by a member of the Institutional Review Board (IRB) of NorthShore University HealthSystem. The above referenced revision qualifies for expedited review because the sponsor's changes to the consent form do not alter the risk of the study.

IRB Approved Enrollment (incl. screen failures): **75**

The revision was approved by expedited review in accordance with the Code of Federal Regulations (45 CFR 46 - as revised and 21 CFR 50, 56, as applicable) on the date of this letter. The NorthShore University HealthSystem Institutional Review Board has an approved assurance of compliance with OHRP which covers this activity (Federal Wide Assurance: FWA00003000).

A revised Consent Form is enclosed with this letter. Please destroy any previous versions and use this one for the study. You are required to keep the original signed Consent Forms in your files.

It is noted that this revision did not include modifications to the Assent form; therefore, does not affect the previously determined Subpart D level of risk (404).

Sincerely yours,

DocuSigned by:

Kevin Novak, Ph.D.



Signer Name: Kevin Novak, Ph.D.

Signing Reason: I approve this document

Signing Time: 5/20/2022 | 4:18 PM CDT

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Kevin Novak, Ph.D.

Member, Institutional Review Board

/dyc

cc: Olivia Keaveny, Research Manager, Department of Medicine
Holly Jacobs
Lynn Tucker