Notification of Reapproval

Date: February 24, 2020

Principal Investigator: Sophie Molholm

Study Title: Human Clinical Phenotyping Core
IRB #: 2011-320

Reference #: 060858

Approval Date: 02/24/2020

Expiration Date: 02/23/2021

This is to inform you that the Einstein IRB has reviewed and reapproved the above referenced human research project and informed consent document(s) for the period noted above by expedited review under 45 CFR 46.110 and 21 CFR 56.110.

To access your reapproved/stamped consents: Go to Study Assistant – My Studies and open the study – Click on Submissions History – Go to Completed Submissions – Locate this submission and click on the Details button to view a list of submitted documents and their outcomes.

Expiration Notice: IRB approval for this study is limited to the period specified above. In order to gain re-approval, you must submit a Progress Report by 01/23/2021. To facilitate this, iRIS will send an email reminder 60 days prior to the due date. When this project is completed, submit a final Progress Report to close the file.

Reminders

Reportable Events must be reported to the IRB in compliance with the Einstein IRB policy.

All changes to a study must receive IRB approval before they are implemented. The only exception to the requirement for prior IRB review and approval is when the changes are necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103(b)(4), 21 CFR 56.108(a)). In such cases, report the actions taken as a reportable event.

For a list of all currently approved documents, follow these steps: Go to Study Assistant – My Studies and open the study – Click on Informed Consent to obtain a list of approved consent documents and Other Study Documents for a list of other approved documents.

Consent form posting requirement for federally sponsored clinical trials receiving initial approval from the IRB after January 20, 2019

The revised Common Rule requires that for each clinical trial conducted or supported by a Federal department or agency (such as the NIH), one IRB-approved informed consent form used to enroll subjects must be posted by the awardee on a publicly available Federal Web site.
The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

At this time, there are two publicly available federal websites that will satisfy the consent form posting requirement: ClinicalTrials.gov and a docket folder on Regulations.gov (Docket ID: HHS-OPHS-2018-0021).

If additional information is needed, please contact the Administrative Office at 718-430-2237.