Principal Investigator Notification:

From: Mayo Clinic IRB

To: Travis Grotz

CC: Travis Grotz
Jennifer Leiting

Re: **IRB Application #:** 18-011434
Title: Analysis of Outcomes in Patients with Peritoneal Carcinomatosis

IRBe Protocol Version: 0.03
IRBe Version Date: 12/28/2018 3:02 PM

IRB Approval Date: 12/28/2018
IRB Expiration Date: 12/27/2021

The above referenced application is approved by expedited review procedures (45 CFR 46.110, item 5). This approval is valid for a period of 3 year(s). The Reviewer conducted a risk-benefit analysis, and determined the study constitutes minimal risk research. The Reviewer determined that this research satisfies the requirements of 45 CFR 46.111.

The Reviewer approved waiver of the requirement to obtain informed consent in accordance with 45 CFR 46.116 as justified by the Investigator, and waiver of HIPAA authorization in accordance with applicable HIPAA regulations.

The Reviewer approved the accrual of 2400 subjects, and to review data that exist between January 1, 2000 through September 30, 2017.

AS THE PRINCIPAL INVESTIGATOR OF THIS PROJECT, YOU ARE RESPONSIBLE FOR THE FOLLOWING RELATING TO THIS STUDY.
1) When applicable, use only IRB approved materials which are located under the documents tab of the IRBe workspace. Materials include consent forms, HIPAA, questionnaires, contact letters, advertisements, etc.
2) Submission to the IRB of any modifications to approved research along with any supporting documents for review and approval prior to initiation of the changes.
3) Submission to the IRB of all Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO) and major protocol violations/deviations within 5 working days of becoming aware of the occurrence.
4) Compliance with applicable regulations for the protection of human subjects and with Mayo Clinic Institutional Policies.

Mayo Clinic Institutional Reviewer