Informed Consent Statement

Re: IRB#2021-035: A retrospective Comparison Study of Patients with Hepatitis C and Type 2 Diabetes Mellitus vs. Patients with Type 2 Diabetes Mellitus- Transient Elastography Findings.

Jurisdiction: Medical Records at Saint Vincent Medical Center, 123 Summer Street, Worcester, MA 01608

Dates: 02/17/2010 through 3/09/2021

Continued approval is conditional upon your compliance with the following requirements:

- The following must be promptly reported to the IRB: changes to the study site, and all unanticipated problems that may involve risks or affect the safety or welfare of subjects or others, or that may affect the integrity of the research.
- Approval is valid for enrollment of the number of subjects indicated on your submission form.
- All protocol amendments and changes to approved research must be submitted to the IRB and not be implemented until approved by the IRB except where necessary to eliminate apparent immediate hazards to the study subjects.
- Compliance with all federal and state laws pertaining to this research, and with MetroWest Medical Center IRB's SOPs
- A waiver of consent was approved in accordance with 45 CFR 46.116(e) 1.
- All publications and communications related to this research are subject to Tenet Policy AD 2.16 related to the substantiation of all data/claims with reliable scientific evidence.

Additionally, a HIPAA Waiver of Authorization has been approved as it relates to the conduct of the above named study.

If data is collected from or shared with another institution/facility a data use agreement must be in place

Please call me if you have any questions about the terms of this determination at 508-383-8786 or e-mail me at mary.oster@mwmc.com .

Sincerely,

Mary Oster
IRB Administrator