



METROWEST MEDICAL CENTER

Framingham Union Hospital • Leonard Morse Hospital

October 26, 2020

Russell Weisz, M.D.
Trauma Medical Director
Delray Medical Center
5352 Linton Blvd.
Delray Beach, Florida 33484

RE: 2020-138: HIP FRACTURES ADMISSION PATHWAYS TO SURGERY

Jurisdiction is for records at Delray Medical Center 5352 Linton Blvd, Delray Beach, Florida
Dates: 01/01/2016 to 06/30/2020

Dear Dr. Weisz:

This is to inform you that on October 26, 2020 MetroWest Medical Center Institutional Review Board (IRB), via Expedited Review by the IRB Chair, has approved the above-referenced research protocol and the participation of the above-referenced investigative site in the research. Your study number is 2020-138. Please be sure to reference this number and the name of the principal investigator in any correspondence with MetroWest Medical Center IRB.

The following items were in this submission of October 23, 2020:

- Site submission form
- Study Protocol
- Completed Chart review protocol form
- HIPPA Waiver of Authorization
- Codes linking sites
- Variables for Hip Fxs
- CVs, Medical License and training certificate for Russell Weisz, M.D. and Ivan Puente, M.D.

Specifically your request was approved as "expedited review" under the following category:

- Secondary research uses of identifiable private information or identifiable biospecimens that are not exempt under § __.104(d)(4) because (a) the identifiable private information or identifiable biospecimens are not publicly available; (b) information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of human subjects can be readily ascertained directly or through identifiers linked to the subjects, or the investigator intends to contact the subjects or will re-identify subjects; (c) research use of identifiable health information not regulated under 45 CFR parts 160 and 164, subparts A and E.

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

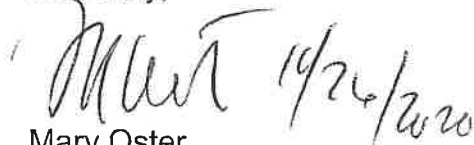
- The following must be promptly reported to the IRB: changes to the study site, and all unanticipated problems that may involve risks or affect the safety or welfare of subjects or others, or that may affect the integrity of the research.
- Approval is valid for enrollment of the number of subjects 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,

Handwritten signature of Mary Oster in black ink, with the date 1/24/2020 written next to it.

Mary Oster
IRB Administrator