



To: Beth Radtke
From: Gretchen Parker, IRB Chair
Subject: Protocol #20-AAPM-101
Date: 06/24/2020

Institutional Review Board has reviewed the documents submitted for exemption determination in accordance with FDA 21 CFR 56.104 and DHHS 45 CFR 46.104 regulations and has approved the request. The protocol **20-AAPM-101. The American Academy of Physical Medicine and Rehabilitation (AAPM&R) Quality Registry Project** has been determined by the Institutional Review Board to be **Exempt** according to FDA 21 CFR 56.104 and 45CFR46.104(b)(4): (4) Secondary Research Uses of Data or Specimens on 06/24/2020.

Please note that changes to your protocol may affect its exempt status. The exempt determination is valid for the life of the research unless a change(s) is made that requires an additional review. This approval does not apply to studies enrolling prisoners.

Pearl IRB may revoke an exemption in the event of non-payment or if the Investigator or Sponsor deviates from the protocol without prior IRB review. Payment is due at the time of review, as soon as an invoice is received from the Pearl IRB billing department. If the study is no longer determined to be exempt, all project activities must cease immediately, including data analysis and any resulting data or analysis is null and void. Terminated studies are not considered completed.

You may download study documentation directly from your Mentor account. If you have any questions, please contact Pearl IRB.

Best,

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