Office of Human Subjects Research
Institutional Review Boards

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Date: September 9, 2024

APPLICATION APPROVAL

Review Type:	Convened
Principal Investigator:	Christopher Mecoli
Number:	IRB00373992
Title:	OHDSI Dermatomyositis Phenotype Development and Evaluation
Committee Chair:	Howard Lederman
IRB Committee:	IRB-1

Date of Approval: September 3, 2024

Date of Expiration: September 2, 2025

The JHM IRB approved the above-referenced Application.

The Board determined that this study presents no more than minimal risk and can be reviewed using an expedited review process in the future (expedited category 9).

The Board recommended that the PI submit a progress report after 1 year.

IRB review included the following:

45 CFR 46.116: A waiver of consent was granted based on the following criteria: 1) the research involves no more than minimal risk to subjects; 2) the waiver will not adversely affect the rights and welfare of the subjects; 3) the research could not be practicably carried out without the waiver; and 4) the IRB will advise you if it is appropriate for participants to be provided with additional pertinent information after participation.

Progress Report Required:

The Board determined that this research meets the criteria for submission of a Progress Report as an alternative to a Continuing Review Application. The Progress Report must be submitted using a Further Study Action and selecting progress report at least 6 weeks prior to the expiration date. Please note, the Progress Report **must** be submitted prior to the expiration date shown on this notice. If the Progress Report is not acknowledged prior to the expiration date all activity must stop and the application will enter a state of "Progress Report Past Due".

Changes in Research: All proposed changes to the research must be submitted using a Change in Research application. The changes must be approved by the JHM IRB prior to implementation, with the following exception: changes made to eliminate apparent immediate hazards to participants may be made immediately, and promptly reported to the JHM IRB.

Unanticipated Problems: All unanticipated problems must be submitted using a Protocol Event Report.

If this research has a commercial sponsor, the research may not start until the sponsor and JHU have signed a contract.

The JHMIRB is constituted to meet the requirements of the Privacy Rule at section 45 CFR 164.512(i)(1)(i)(B) and is authorized and qualified to serve as the Privacy Board for human subjects research applications conducted by Hopkins' faculty members. The JHM IRB reviewed your request to waive or alter authorization for the above-referenced project. The IRB determined that all specific criteria for a waiver or alteration of authorization were met, as follows:
(A) The use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals, based on, at least, the presence of the following elements;
(1) An adequate plan to protect the identifiers from improper use and disclosure;
(2) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
(3) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted;
(B) The research could not practicably be conducted without the waiver or alteration; and
(C) the research could not practicably be conducted without access to and use of the protected health information.

Study documents:

HIPAA Form 4:
FINAL_Mecoli_IRB00373992_HIPAA Form 4_9.3.24.doc

Additional Supplemental Study Documents:
ohdsi_dematomyositis_phenotype_evaluation_20240612.pdf

Protocol:
IRB00373992_eFormS_20240807_clean.docx

Johns Hopkins Study Team Members:

Benjamin Martin, Will Kelly