**KATHY HOCHUL**
Governor

**MARY T. BASSETT, M.D., M.P.H.**
Commissioner

**KRISTIN M. PROUD**
Acting Executive Deputy Commissioner

DATE: March 11, 2022

TO: Aida Soim, PhD, MD

FROM: Robin Krause, MS - IRB Administrator II New York State Department of Health Institutional Review Board

PROJECT TITLE: [765435-12] Surveillance and Epidemiologic Research of Duchenne and Becker Muscular Dystrophy

REFERENCE #: 03-062

ACTION: RESEARCH QUALIFIES FOR EXEMPT CATEGORY # Exempt Category 2 and 4(iii)

DECISION DATE: March 11, 2022

The New York State Department of Health Institutional Review Board (IRB) has reviewed your amendment request to add a survey to the study referenced above. Upon review, the IRB re-evealuated the Expedited desgination and found that this study is eligible for Exempt Categorization. The IRB has determined that this project meets the criteria for research exempt category 2 for the survey being added with the submitted amendment **(45 CFR 46.104 (d)(2)) - Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior including visual or auditory recording:** Applicability to vulnerable populations: pregnant women are eligible for this type of research; prisoners are eligible ONLY for research that is aimed at a broader population but may incidentally include prisoners. Children are eligible ONLY for research with educational tests and passive observations of public behavior that do not require limited IRB review and Exempt Category 4(iii) for the use of the surveillance part of this study to inform the selection of survey participants: **Category 4 (45 CFR 46.104 (d)(4)) - Secondary research data for which consent is not required. It only applies to the re-use of data and specimens that were or will be collected for non-research purposes or from research studies other than this proposed research study.** Applicability to vulnerable populations: pregnant women and children are eligible for this type of research; prisoners are eligible ONLY for research that is aimed at a broader population but may incidentally include prisoners. Secondary research uses identifiable private information or identifiable biospecimens, such as retrospective or prospective use of data, documents, records, pathological specimens or diagnostic specimens.The investigator's secondary use of the identifiable private information is regulated under HIPAA as "healthcare operations," "research," or public health."

*This study qualifies for a HIPAA Waiver under the HIPAA Authorization Criteria (45 CFR 164.512(i)(2) and a Waiver of Documenting Informed Consent Waiver under the criteria that the study is minimal risk and only involves procedures for which consent is not normally sought outside the research context.*

The IRB has approved your amendment to add the survey and recategorized your study.

Per federal regulations 45 CFR 46.101(b) studies designated as exempt will not be assigned an expiration date, do not have to undergo annual continuing review, and are able to initiate minor staff and

protocol changes without IRB approval. However, Exempt Category Research Study PIs are required to notify the IRB regarding significant changes that affect the aims of the protocol and the risk/benefit ratio prior to implementing those changes. Please note: If you are unsure if your protocol change falls under the minor category, please contact IRB Administration for guidance.

***The PI is required to respond to IRB inquiries in a timely manner and informing the IRB when the study is completed. Your study does not currently have an anticipated completion date and the IRB will check in with you on March 11, 2025 unless the study is completed prior to that date. If you are extending this project past this date, please let the IRB know, otherwise, you may email the IRB when the study is completed.***

Please note: IRBNet is not to be used as the PI's research record database. Research records should be maintained on a NYSDOH secure server.

If you have any questions, please contact the IRB at 518-474-8539. Please include your project title and reference number in all correspondence with this committee.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within New York State Department of Health Institutional Review Board's records.