EXEMPT DETERMINATION

DATE:	18 Sep 2026
TO:	Lisa Roche
PROJECT:	National Center for Advancing Translational Sciences(NCATS), National Institutes of Health (NIH N3C_ClinicalDataTransfer_v2026_0402, NCATS National Clinical Cohort Collaborative (N3C) Clinical Data Transfer Protocol (PRO04043630)

DOCUMENTATION REVIEWED:

Protocol Version(s):

- Protocol (Dated March 3, 2026)
- NCATS National Clinical Cohort Collaborative (N3C) Enclave DATA USE AGREEMENT (Version 1.0, Dated August 18th 2026)
- NCATS' National Clinical Cohort Collaborative (N3C) Enclave DATA TRANSFER AGREEMENT (Dated 12-11-2025)
- LINKAGE HONEST DATA BROKER AGREEEMENT (Dated 4/22/2026)
- National Clinical Cohort Collaborative (N3C) - Dynamic Workspaces (Version 8, 20 March 2025)

Using the Department of Health and Human Services regulations found at 45 CFR 46.104(d) (4the IRB determined that your research project is exempt from IRB oversight. All study related documents will be removed from our active files and archived.

Note: You will still be able to access this study via the Advarra CIRBI Platform under the "Archived" tab on your Dashboard for three years. After three years, the study will be removed from the system in accordance with IRB regulations.

Please be advised that as Advarra IRB is not overseeing the conduct of the study, study materials, documents and reports should not state that the study is "approved" by an IRB. Also, if your study includes subject-facing materials such as consent forms, recruitment materials, and other materials used by subjects in the study, the IRB company name and contact information should not be referenced. Study materials, documents and reports may include a general statement that the study was reviewed by an IRB, such as, "This study has been reviewed by an institutional review board (IRB), which is a committee that has reviewed this research study to help ensure that your rights and welfare as a research participant are protected and that the research study is carried out in an ethical manner."

The IRB granted this exemption with an understanding of the following:

1. The research project will only be conducted as submitted and presented to the IRB, without additional change in design or scope.

Copyright 2026 Advarra, Inc.

2. Should the nature of the research project, or any aspect of the study, change such that the nature of the study no longer meets the criteria found in 45 CFR 46.104(d)(4), you will resubmit revised materials for IRB review.

3. It is the responsibility of each investigator to ensure that the project meets the ethical standards of the institution. Specifically, the selection of subject is equitable, there are adequate provisions to maintain the confidentiality of any identifiable data collected, and when there are interactions with research subjects, they will be informed: that the activity involves research; of a description of the procedures; that participation is voluntary; and of the contact information for the researcher.

The IRB will evaluate the new information and make a determination at that time regarding the research project's status.

Documentation of Full HIPAA Waiver

The IRB has granted the Full Waiver of HIPAA Authorization after determining that the waiver of authorization satisfies the criteria set forth in the HIPAA Privacy Rule at (45 CFR 164.512(i)(2)).

The waiver of authorization was reviewed and granted under expedited review procedures. The IRB has determined that the protected health information necessary to be used/accessed is as outlined in the protocol and/or IRB application.

This project is not subject to requirements for continuing review.

If you wish to appeal the IRB's determinations and/or imposed modifications, please submit supporting documentation to address the IRB's concerns by creating an Appeal Modification in CIRBI.

Compliance Statement/REB Attestation (Applicable for research conducted in Canada):

The membership of the IRB complies with the requirements defined in Health Canada regulations, ICH GCP guidelines, FDA regulations at 21 CFR part 56, and HHS regulations at 45 CFR part 46. The IRB carries out its functions in accordance with FDA regulations at 21 CFR parts 50, 56, 312, and 812; HHS regulations at 45 CFR part 46, subparts A-E; good clinical practices; Health Canada regulations; and the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, as appropriate to the research.

Advarra IRB is registered with OHRP and FDA under IRB#00000971.

Please review the IRB Handbook located in the "Reference Materials" section of Advarra CIRBI™ Platform (https://cirbi.advarracloud.com). A copy of the most recent IRB roster is also available.

If you have any questions, please feel free to contact us at 410-884-2900.

Copyright 2026 Advarra, Inc.

Thank you for selecting Advarra IRB to review your research project.

Sincerely,



Luke Gelinas, PhD
Executive Board Chair

Copyright 2026 Advarra, Inc.