



**DATE:** 17-Mar-2021 (Letter revised to remove conflicting determination language 31-Aug-2021)

**TO:** Paul A Harris, PhD

**CC:** Carrie D. Wolinetz, PhD  
Joshua Denny, MD, MS

**FROM:** *All of Us* Institutional Review Board Operations Office

**RE:** Not Human Subjects Research Determination: Research Hub: Controlled Tier Data Access Process for the *All of Us* Research Program

*AoU* IRB Protocol Number: 2021-02-TN-001

Protocol Title: All of Us Research Program (All of Us)  
Principal Investigator: Paul A Harris, PhD  
Determination Date: 17-Mar-2021

Thank you for submitting this request for a not human subjects research determination. The *All of Us* Institutional Review Board (*AoU* IRB) Operations Office staff reviewed the request and determined activities utilizing the “Controlled Tier” do not constitute research involving human subjects. 45 CFR 46 [Common Rule 2018] does not apply to a researcher’s use of data available via the “Controlled Tier”. Thus, individual projects utilizing controlled tier data access do not need to be reviewed and approved by the *AoU* IRB.

The following document was reviewed:

- Controlled Tier Determination Request [19-Feb-2021]

The All of Us IRB notes the following:

- 1) The Chair and Vice Chair in consultation with *AoU* IRB members and the Director of IRB Operations agreed with the *All of Us* Research Program the proposed Controlled Tier Data Access Process for the *All of Us* Research Hub is in alignment with the *All of Us* Research Program consent process.
- 2) As the proposed Controlled Tier Data Access Process for the *All of Us* Research Hub is not research involving human subjects, access to data from the Controlled Tier can be granted without individual research project review by the *AoU* IRB.
- 3) The Chair and Vice Chair in consultation with *AoU* IRB members and the Director of IRB Operations acknowledge varying institutional perspectives on what data, alone or in combination, could be considered as making an individual participant’s identity readily ascertainable per definition in the 2018 Common Rule [(45 CFR 46.102(e)(5)]. Investigators accessing the Controlled Tier in their role as an agent of an institution should be mindful that the disposition of the *All of Us* IRB may not absolve them of requirements at the institutional level.

This determination applies only to the activities described in this request and listed below. Any changes to the proposed activity may result in a change to this determination. If changes are being considered, please contact the *All of Us* IRB Operations Office staff at [pmiirb@emmes.com](mailto:pmiirb@emmes.com) prior to implementation.

NKass 9.8.21

**Signature:** *Nancy Kass*  
Nancy Kass (Sep 8, 2021 07:37 EDT)  
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Dmagnus 9.8.21

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# All of Us IRB ControlledTier Revised Letter 08312021

Final Audit Report

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