

**From:** [Mychaleckyj, Josyf C \(jcm6t\)](mailto:Mychaleckyj.Josyf.C@jcm6t)  
**To:** [Franceschini, Nora](mailto:Franceschini.Nora)  
**Subject:** Fwd: Scientific review complete for your TOPMed single PI paper proposal 8404  
**Date:** Thursday, November 21, 2019 8:14:14 AM

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We have approval.

Thanks, Joe.

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Josyf C. Mychaleckyj, MA DPhil  
Associate Professor, Public Health Sciences  
Assistant Director of Bioinformatics & Genetics  
Center for Public Health Genomics  
University of Virginia, PO Box 800717  
Charlottesville, VA 22908-0717  
Tel: +1 (434) 982-1107

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Begin forwarded message:

**From:** TOPMed Publications <[ttmpubs@uw.edu](mailto:ttmpubs@uw.edu)>  
**Subject:** Scientific review complete for your TOPMed single PI paper proposal 8404  
**Date:** November 20, 2019 at 5:19:46 PM EST  
**To:** "[jcm6t@virginia.edu](mailto:jcm6t@virginia.edu)" <[jcm6t@virginia.edu](mailto:jcm6t@virginia.edu)>  
**Cc:** "[ssr4n@virginia.edu](mailto:ssr4n@virginia.edu)" <[ssr4n@virginia.edu](mailto:ssr4n@virginia.edu)>, "[jrotter@labiomed.org](mailto:jrotter@labiomed.org)" <[jrotter@labiomed.org](mailto:jrotter@labiomed.org)>

*Sent on behalf of the TOPMed Publications Committee*

Dear Dr. Mychaleckyj:

**Congratulations!** The scientific review of your paper proposal, [DNA methylation and kidney outcomes in the Multi-ethnic Study of Atherosclerosis](#), has been completed by the reviewers in the TOPMed Publications Committee. As a [single PI proposal](#) this review is advisory only, but comments are provided below for your benefit. The single PI you specified in this proposal is copied on this email, as well as the Co-PI.

The next step for your paper proposal is the [selection of the data sets you would like to use](#). As a single PI proposal, subsequent approval of those selections will likely come from you or members of your team that are designated as the data set contacts. However, this step is still necessary and is quick to complete.

You can begin analysis as soon as the data sets are approved and sequence and phenotype data are in hand (including harmonized phenotypes for cross-cohort analyses).

We encourage your collaboration with other TOPMed studies and your participation in relevant TOPMed working groups in carrying out these studies.

Although you have completed the scientific review process for your paper proposal, you may also find this overview of the entire [paper proposal submission process](#) useful along with the following links:

- [TOPMed Publications Policy](#)
- [Instructions for submitting revisions to a paper proposal](#)
- [Paper Proposal Viewer](#)
- [Update the status of your paper proposal from your Dashboard](#)
- [TOPMed Manuscript Writing and Submission Guidelines](#)

Thank you very much for taking the time to write these proposals. Your efforts on behalf of TOPMed are very much appreciated.

Best wishes,

The TOPMed Publications Committee

Scientific reviewers' anonymized comments:

- Review Date: 11/14/19  
Review Status: Approve  
Review Comments: single study proposal
- Review Date: 11/11/19  
Review Status: Approve  
Review Comments: No concerns
- Review Date: 11/10/19  
Review Status: Approve  
Review Comments: No concerns
- Review Date: 11/08/19  
Review Status: Approve  
Review Comments: no concerns
- Review Date: 11/06/19  
Review Status: Approve  
Review Comments: No concerns
- Review Date: 11/06/19  
Review Status: Approve  
Review Comments: none
- Review Date: 11/06/19  
Review Status: Approve  
Review Comments: No concerns
- Review Date: 11/06/19  
Review Status: Approve  
Review Comments: Approve



**Research  
with Heart.**

## Memorandum

**To:** Anna Kottgen  
**From:** Richey Sharrett, for the ARIC Publications Committee  
**CC:** ARIC Publications Committee; Hunter Holbrook  
**Subject:** Review of ARIC MS # T1256

Title: Discovery of rare genetic variants from whole genome sequencing analyses of kidney function (eGFR) in 23,732 participants from multi-ethnic populations: the Trans-Omics for Precision Medicine (TOPMed) program

**Date:** Wednesday, November 13, 2019

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On behalf of the ARIC Steering Committee, I am happy to inform you that the above-referenced paper has been approved.

ARIC Publication Policies Require:

1. To comply with NIH Public Access Policy, all ARIC manuscripts are required to be submitted to PubMed Central upon acceptance for publication. If your paper is accepted for publication in a journal that deposits all final published articles in PubMed Central, no author involvement is required. If the journal does not automatically deposit all final manuscripts into PubMed Central, you (or a co-author) **MUST** deposit the final peer-reviewed manuscript in PubMed Central via the NIH Manuscript Submission System (NIHMS): <http://www.nihms.nih.gov/>. More information regarding NIH Public Access Policy can be found here: <http://publicaccess.nih.gov/>
2. Enclosed are the instructions to authors, per our policy, as well as a sentence acknowledging ARIC staff, which should be added to the paper.
3. Please remember to add reference to “ARIC,” in either the title of the paper or the abstract, so that the study can be identified by reference searches. In addition, when the paper has been published, please email the citation and pdf to both Hunter Holbrook ([aricpub@unc.edu](mailto:aricpub@unc.edu)) and Kendra Hay ([aricjhu@jhu.edu](mailto:aricjhu@jhu.edu)).
4. Please follow procedures local to your center for archiving a copy of the programs which created this paper. At Johns Hopkins provide a copy to Natalie Daya ([ndaya1@jhu.edu](mailto:ndaya1@jhu.edu)).

Congratulations and good luck with this interesting paper’s submission.



## MEMORANDUM

Date: November 15, 2019

To: Bridget Lin  
Nora Franceschini

From: Lindsey Bull  
P&P Committee Coordinator

Subject: Manuscript 4056 – Discovery of rare genetic variants from whole genome sequencing analyses of kidney function (eGFR) in 23,732 participants from multi-ethnic populations: The Trans-Omics for Precision Medicine (TOPMed) program

Congratulations! The Publications and Presentations (P&P) Committee has approved this paper with recommended changes. Please see the reviews at the end of this memo for details.

You may now submit your manuscript for publication. It is important to keep WHI updated of your manuscript's status on an ongoing basis. Please notify P&P when your manuscript is submitted to a journal and accepted for publication by e-mailing ([p&p@whi.org](mailto:p&p@whi.org)). As they become available, please send (1) a copy of the manuscript as accepted by the journal, (2) the published manuscript in PDF form, and (3) the NIH Manuscript Submission number/PubMed Central number. Authors are required to submit their published manuscript to PubMed Central; see <http://publicaccess.nih.gov> if you are unfamiliar with the NIH Public Access Policy.

Please be aware that lead authors are responsible for identifying and reporting any conflicts of interest among co-authors and noting these in the final manuscript, per journal requirements. Please ensure that all authors complete and report their conflicts on this paper. In addition, please be sure to keep all co-authors informed of your manuscript's progress. If a journal requires revisions, please solicit and incorporate co-author input and inform the P&P Chairs of any major disagreements among the writing group.

Please be reminded that, in accordance with the data use agreement you signed to obtain WHI data for this paper, the data may only be used for this approved analysis and may not be shared with anyone without authorization from WHI.

At a minimum, consortia/pooling papers must include the following acknowledgements statement: *"The WHI program is funded by the National Heart, Lung, and Blood Institute, National Institutes of Health, U.S. Department of Health and Human Services through contracts HHSN268201600018C, HHSN268201600001C, HHSN268201600002C, HHSN268201600003C, and HHSN268201600004C."* *The authors thank the WHI investigators and staff for their dedication, and the study participants for*

*making the program possible. A full listing of WHI investigators can be found at:*

<http://www.whi.org/researchers/Documents%20%20Write%20a%20Paper/WHI%20Investigator%20Log%20List.pdf>

**From:** [csc.assist@unc.edu](mailto:csc.assist@unc.edu) on behalf of [HCHSAdministration@unc.edu](mailto:HCHSAdministration@unc.edu)  
**To:** [Franceschini, Nora](#)  
**Subject:** HCHS/SOL Pubs Cmte Decision re: Draft MS# 0931 - Discovery of rare genetic variants from whole genome sequence analyses of kidney function in 23,732 people representing multiple ancestries in the Trans-Omics for Precision Medicine program  
**Date:** Friday, December 6, 2019 3:56:55 PM

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Congratulations! The reviewers and the Publications Committee have approved your draft manuscript, please see comments below.

Review comments with suggested/required changes are provided, the Committee feels your paper will be more likely and easier to publish if you incorporate the suggestions.

The study is now reminding all lead authors to use the study name correctly as in the subject of this email. Please when you proof the paper make sure the study name complies with the policies in the "Important Special Notes for Primary Authors / Presenters" posted on the study website at the Resources for Authors page. All papers must be found searching PubMed using the full study name.

First Reviewer –

This is an interesting paper that uses TopMED data to search for novel variants for kidney function. The findings are interesting but are not replicated. Acknowledging that the difficulty of replicating rare and low frequency variants is a problem, the lack of replication needs further discussion and vetting. In fact, the discussion section is “claiming these variants as real” and I don’t think the data necessarily supports this.

Second Reviewer –

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#### Important Notes

1) Genetics and ancillary study papers are not subject to the parent study data verification process. If your paper’s data verification requirement or status for this paper has not been determined, the paper should not be sent to a journal prior to the verification process being completed. You may select to make any required or suggested changes first and then have the verification done, if tables are being revised.

2) All manuscripts are required to use the study name correctly, as in the subject of this email. When you proof the paper ensure that the study name complies with the policies in the "Important Special Notes for Primary Authors / Presenters" posted on the study website at the Resources for Authors page. All papers must be identifiable when searching PubMed using the full study name.

3) Please review and consult <http://sites.csc.unc.edu/hchs> for the wording of acknowledgements and contract numbers etc. A frequently updated list is posted on the Resources for Authors page.

4) If the manuscript includes a NIH co-author, an additional Institute review and sign-off is required. Please confirm with your NIH co-author(s) that their Institutional approval has been secured. Your NIH author is the main contact for this process; however, you may send a note with the draft paper to [NHLBI\\_EBPDOCS@nhlbi.nih.gov](mailto:NHLBI_EBPDOCS@nhlbi.nih.gov) if desired.

5) The Pubs Committee will not need to see the revised draft again if the journal requires minor changes. If revisions are required by a journal, it is expected that you will solicit and incorporate co-author input and inform the Publication Chair(s) of any major disagreements among the writing group. Do ensure that all authors complete and report their conflicts on this paper. In addition, be sure to keep all co-authors informed of your manuscript's progress.

6) Please keep the study updated of your manuscript's status. When your manuscript is submitted to a journal or accepted for publication, please indicate this change by using the Update Manuscript Status button in the My HCHS/SOL Work tab. Once your paper has been published, it will be added to your published work by using the Add to my Published Work tab in the My HCHS/SOL Work tab.

7) It is imperative that all authors submit their published manuscripts to PubMed Central. See <http://publicaccess.nih.gov> if you are unfamiliar with the NIH Public Access Policy. All manuscripts deriving from the HCHS/SOL should be associated with the HCHS/SOL primary contracts and with any applicable ancillary study, or supplement grant numbers, etc.

8) As they become available, please send (1) a copy of the manuscript as accepted by the journal, (2) the published manuscript in PDF form, and (3) the NIH Manuscript Submission number/PubMed Central number.

Thank you for your consideration. We sincerely do appreciate your contribution to the HCHS/SOL!

Contact [HCHSAdministration@unc.edu](mailto:HCHSAdministration@unc.edu) and the Publications Chair, if you have any questions.

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Sent on behalf of the Pubs Committee by HCHS Admin

**From:** [RASIKA Mathias](#)  
**To:** [Franceschini, Nora](#)  
**Subject:** Re: TOPMed manuscript 8517 for study approval  
**Date:** Thursday, December 12, 2019 7:24:19 PM

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Nora, this is good to be submitted. Good luck!

Rasika

Sent from my iPhone

> On Dec 12, 2019, at 5:31 PM, Franceschini, Nora <noraf@unc.edu> wrote:

>

> Hi Rasika:

>

> Please see attached the paper related to this approved manuscript. The draft has been reviewed by GeneSTAR investigators and it needs the final approval for the submission to the journal. We appreciated an expedited review if possible. Thank you for your help.

>

> Best, Nora



**From:** [Jennifer Smith](#)  
**To:** [Franceschini, Nora](#); [Sharon Kardia](#)  
**Subject:** Re: FW: TOPMed manuscript 8517 for study approval  
**Date:** Monday, December 16, 2019 8:27:50 PM

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Hi Nora,  
The GENOA study officially gives approval for this paper.  
Thank you!  
Jen and Sharon

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Jennifer A. Smith, PhD, MPH  
Assistant Professor  
email: [smjenn@umich.edu](mailto:smjenn@umich.edu)

**Department of Epidemiology**  
School of Public Health  
University of Michigan  
1415 Washington Heights, Room 2631  
Ann Arbor, MI 48109-2029  
Tel: (734) 615-9455  
Fax: (734) 764-3192

**Survey Research Center**  
Institute for Social Research  
University of Michigan  
426 Thompson St, Room 3308  
Ann Arbor, MI 48104  
Tel: (734) 936-2603  
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On Fri, Dec 13, 2019 at 10:31 AM Franceschini, Nora <[noraf@unc.edu](mailto:noraf@unc.edu)> wrote:

Hi Jen:

The TOPMed CCC is requesting an official approval by GENOA for the paper (I assume from Kardia) so they will give the ok for the submission to the journal. I think it can be an email stating that the study approve the current version of the paper (attached).

Thank you so much for your help.

Best, Nora

**From:** [Steven Claas](#)  
**To:** [Franceschini, Nora](#)  
**Subject:** Re: TOPMed manuscript 8517 for study approval  
**Date:** Tuesday, December 17, 2019 9:32:05 AM

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Nora -

Ryan Irvin has approved. Donna is traveling, and I've not heard from her. I'll go out on a limb and say that if Ryan approved, so does Donna. Consider agreement to collaborate given.

Steve

On 12/16/19 7:21 PM, Franceschini, Nora wrote:

Let me know if you have any updates on this. I simple email with an statement that the PI has agreed to collaborate in this project should be enough. Best, Nora

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**From:** Steven Claas <[sacl237@uky.edu](mailto:sacl237@uky.edu)>  
**Sent:** Friday, December 13, 2019 10:25 AM  
**To:** Franceschini, Nora <[noraf@unc.edu](mailto:noraf@unc.edu)>  
**Cc:** Arnett, Donna K. <[donna.arnett@uky.edu](mailto:donna.arnett@uky.edu)>  
**Subject:** Re: TOPMed manuscript 8517 for study approval

Nora -

I am seeking HyperGEN final approval as I type this. Should have an answer by end of day.

Administration of GENOA TOPMed work has been split from HyperGEN (despite being funded as a unit). Please seek approval from Kardia and/or Smith directly for GENOA (if you haven't already).

Cheers,

Steve

On 12/13/19 9:13 AM, Franceschini, Nora wrote:

Hi Steve, the TOPMed CCC is requesting an email confirming that HyperGEN and GENOA approved the paper submission. Can you please send me a note about this asap?

Thanks in advance.

Nora

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**From:** Franceschini, Nora  
**Sent:** Thursday, December 12, 2019 5:21 PM  
**To:** [steven.claas@uky.edu](mailto:steven.claas@uky.edu)  
**Cc:** [donna.arnett@uky.edu](mailto:donna.arnett@uky.edu)  
**Subject:** FW: TOPMed manuscript 8517 for study approval

Hi Steve:

Please see attached the paper related to this approved manuscript. The draft has been reviewed by HyperGen and GENOA investigators and it needs the final approval for the submission to the journal. We appreciated an expedited review if possible. Thank you for your help.

Best, Nora

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Steven Claas  
Senior Research Associate  
University of Kentucky  
College of Public Health  
[steven.claas@uky.edu](mailto:steven.claas@uky.edu)  
651-488-0098

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Steven Claas  
Senior Research Associate  
University of Kentucky  
College of Public Health  
[steven.claas@uky.edu](mailto:steven.claas@uky.edu)  
651-488-0098

**From:** [Mitchell, Braxton](#)  
**To:** [Franceschini, Nora](#)  
**Cc:** [Erickson, Ugur](#)  
**Subject:** RE: TOPMed manuscript 8517 for Amish study approval  
**Date:** Tuesday, December 17, 2019 10:06:11 AM

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Dear Nora,

This is to confirm that the Amish study has approved your kidney function manuscript (#8517) for submission.

Brackie

Let me know if you require anything more.

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**From:** Franceschini, Nora <noraf@unc.edu>  
**Sent:** Tuesday, December 17, 2019 9:59 AM  
**To:** Mitchell, Braxton <bmitchel@som.umaryland.edu>  
**Cc:** Erickson, Ugur <uerickson@som.umaryland.edu>  
**Subject:** RE: TOPMed manuscript 8517 for Amish study approval

**CAUTION:** This message originated from a non UMB, UMSOM, FPI, or UMMS email system. Whether the sender is known or not known, hover over any links before clicking and use caution opening attachments.

Hi Brackie:

The TOPMed DCC is requesting a written note that the Amish study has approved the paper for submission. Could you please send me a note confirming the approval? Thanks in advance.

Best, Nora

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**From:** Franceschini, Nora  
**Sent:** Thursday, December 12, 2019 5:19 PM  
**To:** Erickson at <[uerickson@som.umaryland.edu](mailto:uerickson@som.umaryland.edu)>  
**Subject:** FW: TOPMed manuscript 8517 for Amish study approval

Hi Erik:

Please see attached the paper related to this approved manuscript. The draft has been reviewed by Amish investigators and it needs the final approval for the submission to the journal. We appreciated an expedited review if possible. Thank you for your help.

Best, Nora

**From:** [Walsh, Ann \(NIH/NHLBI\) \[E\]](#)  
**To:** [Franceschini, Nora](#)  
**Subject:** FW: Action required (Levy) TOPMed manuscript NHLBI review requirements  
**Date:** Tuesday, December 17, 2019 12:02:56 PM

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Dear Nora,

This is a confirmation that the FHS has approved the manuscript.

I am awaiting Dan Levy's responses below, so I can send the manuscript to NHLBI.

Thank you for your consideration,  
Ann Walsh

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**From:** Franceschini, Nora <noraf@unc.edu>  
**Sent:** Tuesday, December 17, 2019 11:55 AM  
**To:** Walsh, Ann (NIH/NHLBI) [E] <walshac@nhlbi.nih.gov>  
**Subject:** RE: Action required (Levy) TOPMed manuscript NHLBI review requirements

Let me know if there is an update on the approval. I think I just need an email saying that FHS has approved the paper for submission. This is for the DCC to approve it.

Nora

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**From:** Walsh, Ann (NIH/NHLBI) [E] <[walshac@nhlbi.nih.gov](mailto:walshac@nhlbi.nih.gov)>  
**Sent:** Friday, December 13, 2019 10:29 AM  
**To:** Levy, Daniel (NIH/NHLBI) [E] <[levyd@nhlbi.nih.gov](mailto:levyd@nhlbi.nih.gov)>  
**Cc:** Franceschini, Nora <[noraf@unc.edu](mailto:noraf@unc.edu)>  
**Subject:** Action required (Levy) TOPMed manuscript NHLBI review requirements  
**Importance:** High

Dear Dan,

The attached TOPMed manuscript "Discovery of rare genetic variants from whole genome sequence analyses of kidney function in 23,732 people representing multiple ancestries in the NHLBI Trans-Omics for Precision Medicine (TOPMed) Consortium" requires a response to following questions before NHLBI will review.

NHLBI requires the following verifications from the author and the assembly of manuscript documents. Your responses will be included with the request to NHLBI to review the manuscript-

- 1) Before submitting papers for review, please have the NHLBI author(s) reply to the items below:
  - A. Verify the funding source is acknowledged, if appropriate.
  - B. Verify the disclaimer statement is present. ("The views expressed in this manuscript are those of the authors and do not necessarily represent the views of the National Heart, Lung, and Blood Institute; the National Institutes of Health; or the U.S. Department of Health and Human Services.")
  - C. Verify that there are no critical problems with the clarity of the writing.

- D. Verify that there are no critical problems with the conclusions. They are supported by the data.
  - E. Verify there are no policy-related issues or anything else that would raise any red flags.
  - F. Verify that notification of our press office is not a priority (not newsworthy).
  - G. Verify that the paper is not related to a NIH Commons Fund project. If it does concern a Common Fund project, please attach documentation of NIH Office of Strategic Coordination (OSC) approval, as required on the Common Fund policy here.
- 2) If there are supplemental docs for a paper, please consolidate them into one doc. (So there would be 2 attachments: the main paper and the supplemental information doc.)
  - 3) Which journal will this manuscript be submitted to?

Thank you for your consideration,  
Ann Walsh

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**From:** Franceschini, Nora <[noraf@unc.edu](mailto:noraf@unc.edu)>  
**Sent:** Thursday, December 12, 2019 5:16 PM  
**To:** Walsh, Ann (NIH/NHLBI) [E] <[walshac@nhlbi.nih.gov](mailto:walshac@nhlbi.nih.gov)>; [kmutalik@bu.edu](mailto:kmutalik@bu.edu)  
**Subject:** TOPMed manuscript 8517 for FHS approval

Hi Ann:

Please see attached the paper related to this approved manuscript. I had received input for FHS co-authors and need the final approval for the submission to the journal. We appreciated an expedited revise if possible. Thank you for your help.

Best, Nora