Author’s response to reviews

Title: Clarifying how to deploy the public interest criterion in consent waivers for health data and tissue research

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Author’s response to reviews:

Dear Editor,

We have revised the paper in accordance with the essential revisions you indicated, please see specific responses below.

1. Please change the article type for your manuscript to "Debate" in the submissions system.
   Done.

2. Please format your abstract to include the following subheadings: Background, Main Text, and Conclusions. As such, please separate the "Main text and conclusions" section.
   Main text and conclusion are separated. We also added the following sentence to the conclusion so that it is more substantive and can stand separately.

   “The requirement of public interest for consent waivers in secondary biomedical research should be guided by well-defined criteria for systematic evaluation.”

3. We note that SM and AC are included in the authors list, but are missing from the Authors Contributions section. As such, please be sure to include the contributions of all authors in this section.
   Thank you for noticing this! “All authors” with respect to draft revision and manuscript approval in the last sentence was intended to be inclusive of SM and AVC but it might not have been clear to readers.
Although GOS, GL and I drove the ideas in online discussions, SM and AVC also contributed to the paper’s outline and key arguments in a face to face meeting. I have revised the authors’ contribution statement to reflect this, which should also make it clear that “All authors” include SM and AVC.

4. Please also state the role of the funding body in the design of the study, collection, analysis, interpretation of data, and in writing the manuscript, in the funding section.

GOS added his funding support to the section. The following line on all funders’ role(s) was added. “None of the funding bodies was involved in the analysis, and development and writing of the manuscript.”

5. Please proofread and ensure that when you upload your revised submission it is in the final form for publication. Please remove any tracked changes or highlighting and include only a single clean copy of the manuscript. Should you wish to respond to these revision requests, please include the information in the designated input box only.

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