Dear Annette Flanagin, Dr. Christakis and the Editorial Board and Office of JAMA Pediatrics,

Thanks for getting back to us and requesting clarification, which we are happy to provide. We have put your questions in italics and our answers below.

*1. Please address questions of fact and measurement accuracy raised about the study without editorializing or admonishment.*

 *2. We are specifically interested your response to the concerns about the G100 CO2 incubator and PCE-CMM 10 analyzers used in the study. If you have additional independent evidence for their accuracy and validity as measurement instruments for this type of study, please provide references.*

This type of measurement has not been conducted before except in one case1 and there is no dedicated equipment for measuring CO2 content of air within a face mask. The **G100 CO2 incubator analyzer** was designed to verify CO2 content in closed spaces, such as in an incubator. But there is no reason why it should not be used in a situation such as ours, if the calibration data and the measurement accuracy data are appropriate. In our case they are.

We attach the calibration fact sheet (Dec. 2020; the device was newly purchased). It gives the ranges of accuracy: 0 – 20 vol% CO2 (we only used the range between 0 – 5 vol%), the imprecision is ±1% of the calibrated value. The calibration of the device by the manufacturer with standard gases states a precision between 0.064 and 0.080 vol %, hence we take it to be 0.1 vol %. There is one other study which used the same apparatus 1, which we quote in the long version of our paper. It was conducted by a group of doctors and engineers in South Tyrol, Italy, and we attach an English translation. To our knowledge it is not published yet.

The operating manual states (p. 27 highlighted and attached) that the sensor reacts to changes in gas content within 1 – 2 seconds. Together with the tube the response time is longer, about 15 to 20 seconds. We took this into account by waiting for 30 seconds until we took the data and by only measuring the same type of air (e.g. only joint inhaled and exhaled air for 3 minutes, i.e. continuous measurement, then 3 minutes only measurement during inhalations, then 3 minutes only measurement during exhalation, always interspersed with a break).

The **PCE-CMM 10** measurement device is a device specifically designed for workplace safety monitoring to measure air quality: CO2 content of ambient air, humidity and temperature. It measures CO2 in a range from 400 to 5.000 ppm with a resolution of 1 ppm and a precision of ±5% +50 ppm in the range between 400 and 2.000 ppm. It was used for ambient air measurement only, which was around 1.000 ppm.

*3. Please also provide published evidence to support the key assumption that the CO2 levels inside the mask reflect inhaled CO2 levels.*

It is not a key assumption that CO2 levels inside the mask reflect inhaled air. To our knowledge we have never said that nor made this assumption. What we say is that it can be assumed that the air which is breathed in is a mixture of the fresh air coming in through the fabric and the dead space volume of the mask which accumulates the CO2 from exhaled air into the mask. We measured the CO2 content of inhaled, exhaled and joint inhaled and exhaled air. The latter is accumulated in the dead space volume under the mask. We achieved this by fixing a measurement tube at the face between nose and upper lip. Hence, our values reflect CO2 content that is inhaled or exhaled. This will always be a mixture of the air that comes in freshly through the mask, mixes with the air that is trapped in the dead space volume likely because of diffusion time lag and is then breathed in again. To our knowledge there is no publication of the CO2 content of the mask itself.

*4. Address the additional comments posted since you drafted your initial response. As of today, there are 11 new comments.*

 We address this in an additional document.

*5. Please submit a copy of the more detailed report/full paper version for our assessment.*

This is attached.

*6. Explain what “Mediziner und Wissenschaftler für Gesundheit, Freiheit und Demokratie eV, a public charity” is and how it is related to the subject of your study and if you or any coauthors are affiliated with this organization. Also clarify how this organization “organized” the study and how this aligns with the statement that “The funder had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.”*

 The organization „Mediziner und Wissenschaftler für Gesundheit, Freiheit und Demokratie e.V. (MWGFD)“ translates into „Doctors and Scientists for Health, Freedom and Democracy“. It is a public charity („eingetragener Verein – e.V.“) in Germany. „Eingetragener Verein“ is an instrument of German society where citizens can gather together to pursue activities of common interest. They are registered with local courts and tax offices. Their purpose can range from music, to sports, to nature interest, to scientific or political interests, and they cannot be for profit. MWGFD is such a public charity. It was founded as an organization by medical doctors, citizens and scientists who were critical of the mainstream discourse around the Covid-19 pandemic and irritated by the disruption of critical discourse at universities and in the public media. It works exclusively on the basis of voluntary donations from the public. It has a lose membership organization. Three of the authors (Harald Walach, Andreas Diemer and Ronald Weikl) are members of MWGFD.

The study was initiated and originally planned and organized by Stefan Hockertz, Anna Kappes and Juliane Prentice, none of whom is a member of MWGFD. Through contacts with MWGFD Dr. Traindl was approached to organize the measurements. Dr. Traindl was asked because he is a court-certified and oathbound measurement specialist for workplace safety monitoring, air condition measurement and associated issues. He is in Austria and works for courts in court cases of workplace security. He is not a member of MWGFD. Dr. Traindl wrote the measurement protocol and contributed his measurement expertise. Finally, I was asked to help finalize the protocol and oversee the study as PI.

Thus, the initiative of designing, planning and conducting the study was not by MWGFD, but by independent parents, concerned scientists and citizens. MWGFD helped through its network of contacts and by members participating in the quality assurance. The organization had no influence on the design and on the conduct of the study. It sponsored the actual execution of the study with 2.000 Euro, which went towards financing the expenses of Dr. Traindl, for his travel from Vienna to Germany, the expenses of stay and a support to the purchase of the device, which itself costs 2.000 Euro. None of the other authors received any remuneration or reimbursements.

In that sense we described MWGFD as “sponsor”, because it supported the execution of the study financially. But it did in no way influence the design, the organization or the execution of the study. The analysis was carried out by myself. I also wrote the first draft of the manuscript. All authors were allowed to contribute to the manuscript, but neither was there a direct input into language or interpretation of the paper by MWGFD, nor in any other important decisions regarding the manuscript and its submission. All authors operated on their own behalf and in their own responsibility.

The statement made in the paper that “*the funder had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication”* isaccurate and correct. The situation is structurally similar to authors being part of a charity or university, receiving some traveling expenses from there and conduct a scientific study which is published with the affiliation or the support mentioned but with no further input, regarding content or interpretation.

*7.  Your article states that the study was submitted to the ethics committee of the University Witten/Herdecke, presumably for ethics review. What was the outcome of the review? Was it approved? If so, on what date?*

 The study was submitted to the Ethics Committee of the University Witten/Herdecke. It was reviewed in its session on 10th March 2021 and received a positive vote (dated 19th March 2021) with a few requests of amendment (stratified randomization according to age, balancing of masks, direct informed consent also of children including specialized information sheets for children, not only their parents, ability for children to withdraw from their study at any time on their own accord even against the wish of their parents, exclusion of children with a medical certificate of exemption from mask wearing [this had already been part of the protocol]). The requests for amendment were to be included in an amended protocol and no re-review was foreseen. The chair of the ethics committee told me that this meant we could go ahead provided these changes were incorporated in an amended protocol. This was done and sent to the chair of the ethics committee on March 23rd 2021 via mail and email. The new protocol was also uploaded on the OSF server. Prof. Gaidzik, the chair of the ethics committee notified me via phone that this was sufficient and that we could go ahead. Feel free to contact Prof. Gaidzik, who is chair of medical law and ethics at the University of Witten/Herdecke to verify this: peter.gaidzik@uni-wh.de. Thus, we had ethical approval before we started the study.

8. When you submit your response, be sure to copy all coauthors, as copied on this request.

1. Oberrauch B, Adami M, Gutweniger U, et al. *Ist der Gebrauch von Mund-Nasen-Bedeckungen in der Gesamtbevölkerung eher schädlich als nützlich unter Berücksichtigung der CO2 Konzentration? Luftqualität während des Tragens von Mund-Nasen-Bedeckungen mit Mini-Review [Does the use of a mask covering mouth and nose confer benefit or harm on the population: Air quality while wearing a nose-mouth coverage and mini-review].* Bolzano2020.