

# Exhibit 594

## Child mask mandates for COVID-19: A systematic review

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# Child mask mandates for COVID-19: a systematic review

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## ABSTRACT

**Background** Mask mandates for children during the COVID-19 pandemic varied in different locations. A risk-benefit analysis of this intervention has not yet been performed. In this study, we performed a systematic review to assess research on the effectiveness of mask wearing in children.

**Methods** We performed database searches up to February 2023. The studies were screened by title and abstract, and included studies were further screened as full-text references. A risk-of-bias analysis was performed by two independent reviewers and adjudicated by a third reviewer.

**Results** We screened 597 studies and included 22 in the final analysis. There were no randomised controlled trials in children assessing the benefits of mask wearing to reduce SARS-CoV-2 infection or transmission. The six observational studies reporting an association between child masking and lower infection rate or antibody seropositivity had critical (n=5) or serious (n=1) risk of bias; all six were potentially confounded by important differences between masked and unmasked groups and two were shown to have non-significant results when reanalysed. Sixteen other observational studies found no association between mask wearing and infection or transmission.

**Conclusions** Real-world effectiveness of child mask mandates against SARS-CoV-2 transmission or infection has not been demonstrated with high-quality evidence. The current body of scientific data does not support masking children for protection against COVID-19.

## INTRODUCTION

Mandating masks for children has been one of the most polarising public-health measures implemented during the COVID-19 pandemic. Two Cochrane reviews of randomised controlled trials (RCT) of masking for prevention of upper respiratory infections failed to find a benefit against infection or transmission.<sup>1,2</sup> Most countries have now removed all public mask mandates, while the USA's Centers for Disease Control and Prevention (CDC) and American Academy of Pediatrics continue to recommend masking down to the age of two.<sup>3,4</sup> This recommendation appears to be entirely based on observational data finding associations with lower case rates in masked versus unmasked individuals but does not take into account the potential adverse consequences of masking, especially in young children, including but not limited to impact on speech, language, learning, mental health and physiological factors. Seeing mouth movements

## WHAT IS ALREADY KNOWN ON THIS TOPIC

- ⇒ Child mask mandates have been extensively used as a public health measure during the COVID-19 pandemic.
- ⇒ Masking recommendations appear to be entirely based on mechanistic and observational data, and a systematic review assessing the evidence has not been performed.

## WHAT THIS STUDY ADDS

- ⇒ In this systematic review, 16 studies found no effect of mask wearing on infection or transmission, while six studies reporting a protective association had critical or serious risk of bias.
- ⇒ Because benefits of masking for COVID-19 have not been identified, it should be recognised that mask recommendations for children are not supported by scientific evidence.

## HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

- ⇒ COVID-19-related policy recommendations should be informed by high-quality evidence and consider the possibility of harm, especially for children, who are vulnerable and an ethically protected group.
- ⇒ Healthcare providers and adults working with children should be educated about the absence of high-quality data supporting masking to lower SARS-CoV-2 infection and transmission risks.
- ⇒ Because absence of harm is not established, recommending child masking does not meet the accepted practice of promulgating only medical interventions where benefits clearly outweigh harms.

and facial gestures accelerate word recognition and speech comprehension,<sup>5-8</sup> the integration of facial information is important for speech perception,<sup>9,10</sup> and recognition of facial expressions is critical for children's abilities to communicate and understand and show emotions.<sup>7,11,12</sup> Mask wearing may also cause breathing difficulties, headaches, dermatitis, general discomfort and pain.<sup>2,13-17</sup>

There is an urgent need to base pandemic-related policy recommendations on robust scientific data that include risk-benefit analyses, preferably with the long-term goals and the beneficiaries of the intervention clearly defined.<sup>18</sup> Ethically, children

should be treated as a protected group, where the benefits of any intervention should clearly outweigh harms.

The aim of this systematic review is to evaluate the body of literature on mask wearing in children to assess the existing evidence regarding protection offered by face masks against SARS-CoV-2 infection or transmission.

## METHODS

We conducted a systematic review to evaluate the evidence for effectiveness of child mask mandates in reducing transmission or disease severity in COVID-19.

References were identified through searches of PubMed, Google Scholar, three major preprint servers (SSRN, MedRxiv and Research Square) and major public health agency publication databases and websites until February 2023 (online supplemental appendix 1). We included primary studies of any design investigating mask effectiveness against COVID-19 (SARS-CoV-2) transmission, infection and disease in individuals <18 years old. Publications of case reports, case series, reviews and comments without new data were excluded, as were studies where age groups were not specified or out of the paediatric range, or when the setting or study objective/design were not applicable. The systematic review was prepared according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. The quality risk of bias (ROB) was estimated using the ROB-2 and ROBINS-I tools,<sup>19</sup> a structured approach for assessing the ROB utilising different domains of bias and an overall judgement. All ROB assessments were conducted by two independent reviewers (RD and SNL), and disagreements were resolved by a third reviewer (JS).

## RESULTS

Our literature search identified 597 publications that were screened by title and abstract. We then screened 40 full-text

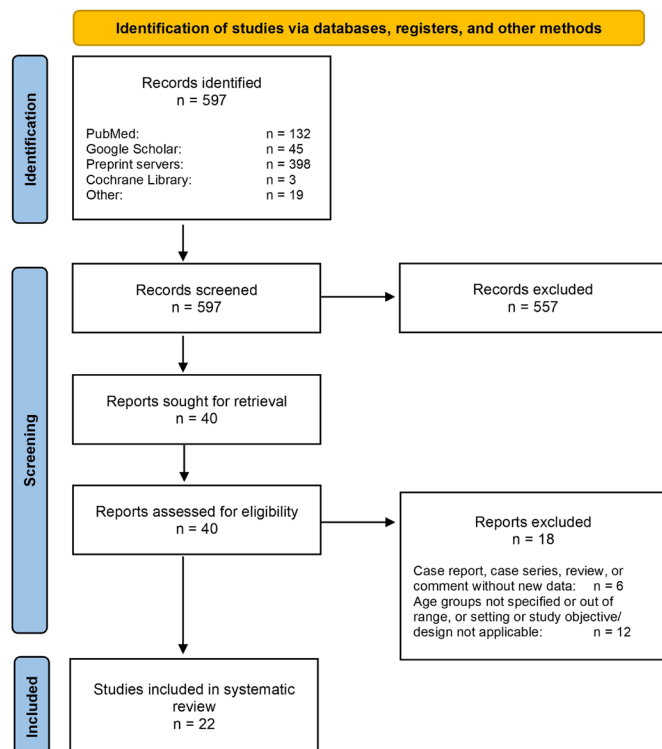
references and excluded 18 that did not meet the inclusion criteria (figure 1). Details of the screened publications are presented in table 1. The ROB analysis by the two reviewers resulted in 18 differences in ratings and four differences in overall ROB that needed to be adjudicated.

To date, there are no RCTs assessing the effects of masking children in reducing COVID-19 transmission or disease. Among the 22 observational studies identified, the overall ROB was critical in six studies (27.2%), serious in 10 studies (45.5%), moderate in five studies (22.7%) and low in none of the studies (table 2). Of the six studies reporting a significant negative correlation between masking and COVID-19 cases, five had critical and one had serious ROB. Of the 16 studies failing to find a significant correlation, 1 (6.3%) had critical, 10 (62.5%) had serious, 5 (31.3%) had moderate and none had low ROB.

All six studies,<sup>20 21 22 23 24 25</sup> reporting a negative association were potentially confounded by crucial differences between masked and unmasked groups, including the number of instructional school days, differences in school size, systematic baseline differences in case rates in all phases of the pandemic, testing policies, contact-tracing policy differences and teacher vaccination rates. These confounders—alone and in combination—resulted in a failure to demonstrate an isolated effect of masks themselves.<sup>20–22</sup>

One study from Boston found that lifting of school mask mandates was associated with increased number of COVID-19 cases,<sup>23</sup> which was questioned upon re-analysis.<sup>26</sup> US studies in North Carolina<sup>24</sup> and Arizona<sup>21</sup> found that mask requirements had negative associations with in-school transmission and COVID-19 outbreaks, respectively. In a 2020 Canadian study published as a preprint, children who did not wear a mask had higher seropositivity than children who wore masks, but the overall seropositivity was low (9/541 or 1.7% in total) and findings were confounded by multiple external factors including social distancing and attendance in schools, social functions and organised sports.<sup>25</sup>

In a Spanish study of almost 600 000 children, the researchers did not find a significant difference in cases between unmasked 5-year-olds and masked 6-year-olds; instead, case rates correlated closely with the age of children,<sup>27</sup> which was also observed in another Spanish study.<sup>28</sup> An observational CDC-funded US study<sup>20</sup> found no significant association between county-wide mask mandates and paediatric case counts on expanded reanalysis.<sup>29</sup> A lack of significant association between masking children and risk of COVID-19 was also reported by the UK Department of Education.<sup>30</sup> In three US studies, there was no correlation between mask mandates and COVID-19 rates,<sup>31</sup> no significant association between COVID-19 incidence and face mask use,<sup>32</sup> and no risk reduction for COVID-19-related outcomes with student mask mandates.<sup>33</sup> Spanish and Irish studies have independently observed similar primary-school COVID-19 transmission in young children with or without masking, respectively.<sup>28 34</sup> In another CDC study, there was no reduction in COVID-19 incidence in schools requiring student masking compared with those with optional masking.<sup>35</sup> When comparing adjacent school districts with and without mask mandates, multiple studies have reported no difference in transmission.<sup>36–38</sup> A Finnish study compared case rates in children with and without mask mandates in 10–12-year-olds, and the authors found no reduction in COVID-19 case rates when mask recommendations were extended to include 10–12-year olds.<sup>39</sup> Face-mask use among high school athletes was not found to have an impact on transmission.<sup>32</sup>



**Figure 1** PRISMA flow diagram. PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

**Table 1** Characteristics of included observational studies

First author, year of study, country	Study design	Child age groups	Sample size	Primary outcome	Main findings
Budzyn, 2021 USA <sup>20</sup>	Case-control study	5–18 years	520 counties	Case detection, based on survey data	Negative association between county-wide mask mandates and paediatric case counts.
Jehn, 2021 USA <sup>21</sup>	Case-control study	5–18 years	Two counties	In-school transmission, based on reported public-health data	Negative association between mask requirements and COVID-19 outbreaks.
Nelson, 2020–21, USA <sup>22</sup>	Cohort study	5–18 years	Eight school districts	In-school transmission, based on reported school-district data	Negative associations between mask requirements and in-school transmission.
Cowger, 2022 USA <sup>23</sup>	Case-control study	5–18 years	72 school districts	Case detection, based on reported school-district data	Negative association between mask requirements and COVID-19 cases.
Boutzoukas, 2021, USA <sup>24</sup>	Cohort study	5–18 years	20 school districts	In-school transmission, based on reported school-district data	Negative association between mask requirements and in-school transmission.
Manny, 2020 Canada <sup>25</sup>	Cohort study	8–13 years	n=565	Seropositivity, based on study testing	Children who did not wear a mask had higher seropositivity than children who wore masks.
Coma, 2021, Spain <sup>27</sup>	Case-control study	3–11 years	1907 schools	Case detection and in-school transmission, based on reported public-health data	No difference in cases between unmasked 3–5 year olds and masked 6–11 year olds; instead, case rates correlated closely with the age of children.
Alonso, 2020, Spain <sup>28</sup>	Cohort study	3–17 years	5104 schools	In-school transmission, based on reported school-district and public-health data	Similar in-school COVID-19 transmission in young children with or without masking, and in-school transmission was age-dependent.
UK Department for Education, 2021, UK <sup>30</sup>	Case-control study	11–16 years	1315 schools	COVID-19 absence rate, based on reported school-district data	No association between masking children and COVID-19 case-rate declines.
Oster, 2020–21, USA <sup>31</sup>	Cohort study	5–18 years	Three US states	Case detection, based on school-district-, self-reported-, and survey data	No correlation between mask mandates and COVID-19 rates.
Sasser, 2020 USA <sup>32</sup>	Cohort study	14–18 years	207 schools	Case detection, based on survey data	No association between COVID-19 incidence and face mask use in high school athletes.
Lessler, 2020–21, USA <sup>33</sup>	Cohort study	4–18 years	One country (selection)	Case detection, based on survey data	No risk reduction for COVID-19-related outcomes with student mask mandates.
White, 2020, Ireland <sup>34</sup>	Cohort study	4–18 years	604 schools	Case detection, based on reported public-health cases	Similar in-school COVID-19 transmission in young children with or without masking.
Gettings, 2020 USA <sup>35</sup>	Cohort study	5–11 years	169 schools	Case detection, based on survey data	No significant reduction in COVID-19 incidence in schools requiring masking.
Tennessee Department of Health and Census, 2021 USA <sup>36</sup>	Case-control study	5–18 years	Two counties	Case detection, based on reported public-health data	No difference in transmission when comparing adjacent school districts with and without mask mandates.
Cabrera, 2021 USA <sup>37</sup>	Case-control study	5–18 years	One county	Case detection, reported school-district data	No difference in transmission when comparing adjacent school districts with and without mask mandates.
Sood, 2021–22, USA <sup>38</sup>	Case-control study	5–18 years	Two school districts	Case detection, based on reported public-health data	No difference in transmission when comparing adjacent school districts with and without mask mandates.
Juutinen, 2021, Finland <sup>39</sup>	Case-control study	7–12 years	Two cities	Case detection, based on reported public health data	No additional benefit in case rates with an extension of mask recommendation to include 10–12 year olds.
Ludvigsson, 2020, Sweden <sup>41</sup>	Cohort study	1–16 years	One country	Morbidity and mortality, based on reported public health data	In Sweden, where schools remained open and masks were not required, only 15 of nearly 2 million children in the country were hospitalised and none died during spring 2020 and infection rate among teachers were similar to that of other professions.
Suryawijaya, 2020–22, Finland <sup>42</sup>	Cohort study	0–17 years	One country	Mortality, based on reported public health data	In Finland, where children have not masked under the age of 10–12 years, no children have died from COVID-19 by March 2022.
Brandal, 2020 Norway <sup>43</sup>	Cohort study	5–13 years	n=292	In-school transmission, based on study testing	In Norway, where masks were not recommended, in-school transmission was <1% among children and <2% in child-adult contacts in schools.
Lam-Hine, 2021 USA <sup>44</sup>	Case series	5–11 years	n=27	In-school transmission, based on reported public health data	Mask usage in a classroom did not prevent transmission from symptomatic adult, while very few of the children infected their family members.

To explore the effect on disease severity, there was no association between viral load of index cases with confirmed COVID-19 and disease severity among secondary cases.<sup>40</sup> In Sweden, where schools remained open and masks were not required, only 15 of the nearly 2 million children were hospitalised and none died during the spring of 2020; also, the infection rate among teachers was similar to that of other professions.<sup>41</sup> In Finland, where children have not worn masks under the age of 10–12 years, no child died from COVID-19.<sup>42</sup> In Norway, where masks in schools have not been recommended, in-school transmission was

<1% among children and < 2% in child-adult contacts during August–November 2020.<sup>43</sup> During a SARS-CoV-2 Delta variant outbreak in a US elementary school in May–June 2021, mask use for staff and students in classrooms did not significantly prevent transmission from symptomatic adults, while very few children went on to infect their family members.<sup>44</sup> In New York City public schools with more than 1600 schools and 1 million enrolled students, the transmission rate (secondary attack rate) during the Delta variant period (October–December 2021) was estimated to be 0.5%.<sup>45</sup>

Table 2 Risk-of-bias rating per study.

Study	Confounding	Selection of participants	Classification of intervention	Deviation from intended intervention	Missing data	Measurement of outcomes	Selection of reported result	Overall risk of bias
Budzyn <i>et al</i> <sup>20</sup>	Critical	Critical	Moderate	Moderate	Critical	Serious	Serious	Critical
Jehn <i>et al</i> <sup>21</sup>	Critical	Serious	Moderate	Moderate	Critical	Serious	Serious	Critical
Nelson <i>et al</i> <sup>22</sup>	Critical	Critical	Moderate	Moderate	Critical	Serious	Serious	Critical
Cowger <i>et al</i> <sup>23</sup>	Critical	Critical	Moderate	Moderate	Critical	Serious	Serious	Critical
Boutzoukas <i>et al</i> <sup>24</sup>	Critical	Critical	Critical	Moderate	Critical	Serious	Serious	Serious
Manny <i>et al</i> <sup>25</sup>	Critical	Moderate	Critical	Serious	Low	Moderate	Critical	Critical
Coma <i>et al</i> <sup>27</sup>	Serious	Serious	Moderate	Moderate	Serious	Moderate	Moderate	Moderate
Alonso <i>et al</i> <sup>28</sup>	Serious	Serious	Moderate	Moderate	Serious	Moderate	Moderate	Moderate
UK Department for Education, 2022 <sup>30</sup>	Critical	Moderate	Moderate	Serious	Critical	Serious	Serious	Moderate
Oster <i>et al</i> <sup>31</sup>	Critical	Critical	Moderate	Serious	Serious	Serious	Serious	Serious
Sasser <i>et al</i> <sup>32</sup>	Critical	Critical	Moderate	Moderate	Critical	Serious	Serious	Serious
Lessler <i>et al</i> <sup>33</sup>	Critical	Critical	Serious	Moderate	Critical	Serious	Serious	Serious
White <i>et al</i> <sup>34</sup>	Critical	Moderate	Critical	Moderate	Low	Moderate	Moderate	Critical
Gettings <i>et al</i> <sup>35</sup>	Serious	Critical	Moderate	Serious	Critical	Moderate	Moderate	Serious
Tennessee Department of Health and Census <sup>36</sup>	Critical	Serious	Moderate	Moderate	Critical	Serious	Serious	Serious
Cabrera <sup>37</sup>	Serious	Moderate	Moderate	Critical	Serious	Serious	Moderate	Serious
Sood <i>et al</i> <sup>38</sup>	Serious	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate
Juutinen <i>et al</i> <sup>39</sup>	Moderate	Moderate	Moderate	Moderate	Moderate	Moderate	Low	Moderate
Ludvigsson <sup>41</sup>	Moderate	Moderate	Critical	Low	Low	Low	Low	Serious
Suryawijaya <i>et al</i> <sup>42</sup>	Critical	Moderate	Low	Critical	Low	Low	Low	Serious
Brandal <i>et al</i> <sup>43</sup>	Critical	Low	Critical	Low	Low	Low	Low	Serious
Lam-Hine <i>et al</i> <sup>44</sup>	Serious	Critical	Serious	Low	Low	Moderate	Low	Serious

## DISCUSSION

In this systematic review on benefits of child masking against SARS-CoV-2, we identified no RCT on the efficacy for use of face masks and the risk of transmission or disease. Among the 22 identified observational studies of masking for prevention of COVID-19, more than 70% of the studies had a critical or serious overall ROB. None of the observational studies reporting a negative correlation between masking and COVID-19 cases had a level of bias that was less than “serious.”

Specifically, of the 6 out of 22 observational studies that reported a significant negative correlation between masking and COVID-19 cases, five had critical and one had serious ROB. Of the 16 out of 22 studies failing to find a significant correlation, only 6.3% had critical ROB, while 62.5% had serious and 31.3% had moderate ROB. Importantly, the largest studies with the lowest ROB did not identify a benefit from masking.<sup>27 28 30</sup> The study (currently in preprint publication) with the most robust internal control showed no benefit from a mask mandate.<sup>38</sup> Observational studies reporting a negative association between masking and COVID-19 rates have failed to demonstrate a benefit when confounding factors have adequately been considered.<sup>20–24</sup> Larger observational studies,<sup>28 31</sup> including a regression-discontinuity analysis<sup>39</sup> and a more robust reanalysis<sup>29</sup> of a prior publication,<sup>20</sup> as well as other observational studies,<sup>27 30 32–38 41–44</sup> failed to find benefit of masking against COVID-19. Observational studies in adults also repeatedly fail to properly adjust for confounding factors to avoid bias.<sup>46–48</sup> Furthermore, the Boston observational study<sup>23</sup> stated they could infer causality between lifting school mask mandates and increases in student and staff cases by using a difference-in-differences technique. However, a subsequent reanalysis called the methodology and results of this study into question and failed to find the same association when

expanding the population to include the entire state or using different statistical analysis and also found the initial study’s results were likely confounded by differences in prior infection rates.<sup>26</sup>

Observational studies have also failed to find an association between voluntary mask wearing among adults in schools and lower odds of COVID-19 in the school<sup>49</sup> or between mask mandates or mask use and reduced transmission.<sup>50</sup> In addition, a systematic review showed a 10-fold lower secondary attack rate in schools compared with community/household settings.<sup>51</sup>

In adults, there are only a limited number of published RCTs of mask wearing and COVID-19 prevention. DANMASK-19 failed to find a 50% reduction in COVID-19 infections in surgical mask wearers in the community.<sup>52</sup> A cluster RCT in Bangladesh found no effect of community cloth masking on COVID-19 infections, no reduction from surgical masking for anyone under age 50, and only a marginal reduction among >50-year olds and in the context of observer-enforced physical distancing,<sup>53</sup> an association that was found to be insignificant after re-analysis.<sup>54</sup> In a predominantly adult cluster RCT of almost 40,000 participants from age 10 and up (but not reported by age group and, therefore, not included in our systematic review), there was no difference in COVID-19-like illness or mortality between masked and unmasked groups.<sup>55</sup> A Cochrane systematic review published in 2020 similarly found use of surgical masks and respirators in adults to have ‘little to no effect’ on the transmission of respiratory viruses, while side effects included discomfort.<sup>1</sup> In the 2023 updated version that included COVID-19, these conclusions remained unchanged.<sup>2</sup>

Perpetual masking in early childhood is without historical precedent. In children, the harms associated with masking are often challenging to identify, measure and quantify with correlational studies, and many of these outcomes will take years to fully evaluate. An extensive body of research has found harms associated with mask wearing or mask requirements in children.<sup>56</sup> These associated harms include negative impacts on speech, language and learning. Mask wearing causes reduced word identification<sup>57–59</sup> and impedes the ability to teach and evaluate speech.<sup>60</sup> There is a link between observation of the mouth and language processing, and people of all ages continue to focus on the mouth when listening to non-native speech.<sup>61</sup> The sensitive period for language development is through age 4, and development of connected speech is ongoing beyond age 10.<sup>62</sup>

Mask wearing may also impact mental health and social-emotional well-being by limiting the ability to accurately interpret emotions, particularly in younger children.<sup>63–66</sup> There is also evidence that masks hinder social-emotional learning and language/literacy development in young children.<sup>67</sup> Children with special-education needs and autism may be disproportionately impacted by mask requirements as they rely heavily on facial expressions to pick up social cues.<sup>68</sup> Misinterpretation of facial expressions increases anxiety and depression in individuals.<sup>69</sup> School environments with mask mandates were also found to have increased anxiety levels compared to those without mandates.<sup>70</sup> In addition, mask wearing has been associated with physiological harm<sup>2 13 13–17</sup>—many of which are more frequently reported in children than in adults<sup>2 17 71</sup>—which may have multiple negative downstream effects, including reduced time and intensity of exercise, additional sick days, reduced learning capacity, and increased anxiety. Masking has also been found to lead to rapid increase in CO<sub>2</sub> content in inhaled air—higher in children than in adults—and to levels above acceptable safety standards for healthy adult workers, which may rise further with physical exertion.<sup>72–74</sup>

In medicine, new interventions with unknown benefit but known or potential risks cannot be ethically recommended or enforced until absence of harm is demonstrated. Rather, the accepted standard is that an intervention should only be employed after benefit has been demonstrated, ideally through an RCT, together with safety data to ensure that proven benefits outweigh harms. The burden of proof to show that an intervention is both safe and beneficial is the responsibility of the person, institution or body implementing and recommending that intervention.<sup>75</sup>

In this systematic review, we fail to find any evidence of benefit from masking children, to either protect themselves or those around them, from COVID-19. Harms of masking may include affected speech, language and emotional development, and physical discomfort contributing to reduced time and intensity of exercise and learning activities, and the long-term effects are too early to be measured. Adults who work with children should be educated about the lack of clear benefits and the potential harms of masking children, and there is no scientific evidence supporting a recommendation for masking in these professions.

In summary, child mask mandates fail a basic risk-benefit analysis. Recommending child masking to prevent the spread of COVID-19 is unsupported by current scientific data and inconsistent with accepted ethical norms that aim to provide additional protection from harm for vulnerable populations.

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