

Enrolling Black Philadelphians in COVID-19 Phase 3 Trials



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1 / Introduction

1.1 Context

There is ample evidence that chronic and infectious diseases disproportionately impact the Black community (Tai et al., 2020), the 2020 COVID-19 pandemic has been no exception. Across the nation, hospitals are reporting a disproportionate number of COVID-19 cases and deaths in the Black community. In Philadelphia, Black individuals account for 55% of COVID-19 related hospitalizations but only 44% of the population (Philadelphia Department of Health, 2020). Additionally, socioeconomic experiences more frequently found in Black communities including, but not limited to, living in crowded housing, inconsistent access to health care, and working in essential fields that are less likely to transition to remote work can further exacerbate the already high risk of community based COVID-19 transmission (Tai et al., 2020).

Increasing the number of Black participants in Phase 3 COVID-19 trials is imperative for vaccine uptake within the Black community. Historically and at present, there is statistically low voluntary participation from the Black community in medical trials. Early in the pandemic, researchers across the country raised serious concerns regarding the prevalent racial disparities across preliminary COVID-19 clinical trials (Borno et. al., 2020). Notably, there is a lack of trust in the medical community due to past and present injustices against Black people, as well as a need for education surrounding the importance of randomized control trials. Increasing participation in current vaccination trials can address both of the aforementioned issues. Promoting diversity in all steps of the COVID-19 vaccine development process will promote more widespread utilization, build trust in a vaccine, and protect lives within the Black community.

1.2 Contributing Factors



Policy factors: Policy plays an important role in the barrier to entry for many minority participants in research studies, specifically Black participants. While research funds often attempt to ensure diversity through various initiatives and requirements for funding, diversity initiatives can be easily circumvented, leading to the concern that regulation is often performative at best (NIH, 2019). At worst, policy can be more sinister toward Black participants, especially in Philadelphia where health care is a major concern to the Black community due to systemic inequities.



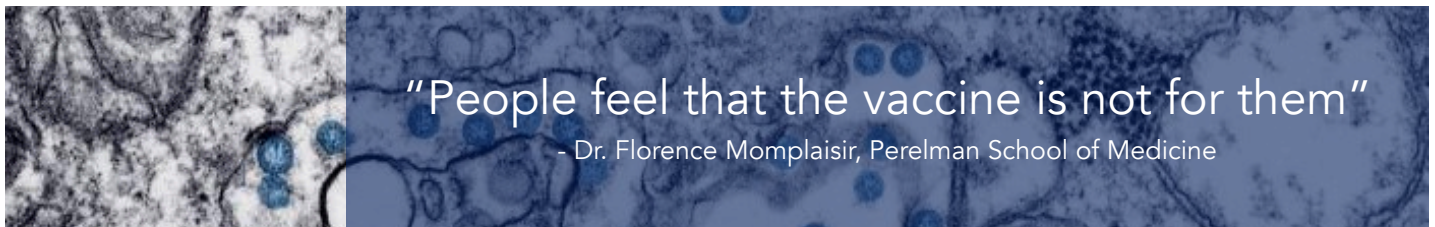
Socioeconomic factors: Existing literature indicates that poverty, unemployment, and low levels of education have contributed to limited awareness of clinical trials and their purposes, as well as challenges of accessibility for Black participants. Information about trials and their safety is typically dependent on internet access or a strong relationship with a trusted health care provider, both of which may be limited or unavailable for those of low socioeconomic status (Ahaghotu et al., 2016). Other economic barriers include hidden costs of participation such as transportation, meals, and limited paid time off from work (Chastain et al., 2020, Legal Monitor Worldwide, 2020).



Interpersonal factors: Previous studies that exploited Black patients, such as the Tuskegee Study, serve as historical examples of why Black patients may be hesitant to participate in research (Aslan & Wanamaker, 2018). Black individuals have also cited disrespect and discrimination from health care providers as a barrier to participate in clinical research (Scharff et al., 2010). Other deterrents from participation in clinical research noted by the Black community include fear that study investigators would not fully explain the research, and exposure to unnecessary risks as a result of research participation (Corbie-Smith et al., 2002).

1.3 Target Behavior

The Black experience with the American medical system and COVID-19 is highly complex and nuanced. Although the field of Behavioral Economics presents a powerful toolkit to tackle societal problems, in order to maximize impact, we felt it was important to narrow the scope of our problem, specifically focusing on the ***underrepresentation of Black participants in COVID-19 vaccine trials***. In the remainder of the paper, we attempt to identify the main behavioral barriers preventing Black individuals from participating in COVID-19 vaccine trials, and suggest interventions to address said behavioral barriers. Ultimately, we aim to increase the number of Black participants in vaccine trials and promote an inclusive, representative study.



2 / Behavioral Insights

2.1 Contextual Inquiry

Understanding the context, sentiment, and challenges associated with this complex issue is imperative to developing impactful behavioral interventions. To build a comprehensive understanding of the many factors at play, we conducted a series of interviews with key stakeholders, reviewed opinion-based sources on the topic, related academic literature, and relevant news sources. Our main findings follow on the next page.

News Sources: The news media has and continues to influence sentiment surrounding vaccine trial participation and eventual uptake, especially given the rapid pace of clinical trial enrollment. For our purposes, a review of news content offered direct insight into the perspective of the Black community and key medical and political stakeholders. Insights reiterated the role of longstanding distrust as a barrier for enrollment, and the importance of clear communication from recruiters and researchers to ensure full understanding of the clinical trial process within the Black community.

Academic Sources: Perspective pieces in academic journals shed light on the current COVID vaccine allocation frameworks provided by the NASEM and CDC, and offered insight into why members of the Black community may be hesitant to enroll in trials. Ideas on how to gain trust gathered from these sources include: transparent consent processes from trial sponsors, ensuring Black communities will have fair access to vaccines once they become available, providing credible evidence that pharmaceutical companies will not submit a vaccine for approval until it is safe, and ensuring appropriate medical care for trial participants.

Interviews: We conducted three interviews with clinical researchers and members of the target population to understand first hand perspectives from individuals with different views on the issue. Key findings centered on the importance of clear and consistent messaging in recruitment, the role of mistrust as a barrier of enrollment, and the plans for equitable vaccine allocation put forth by the National Academies of Science and Medicine (NASEM) and Centers for Disease Control (CDC).

Opinion Based Sources: We used opinion based sources such as Op-Eds to supplement our interview findings. These sources allowed us to gain a more holistic understanding of the issue by adding perspectives from vaccine trial enrollees and Black physicians. The main themes from these sources include mistrust due to historical and ongoing race-based injustices, and the nuances experts suggest addressing as part of the recruitment of Black participants for COVID vaccine trials.

2.2 Behavioral Barriers

The findings from our contextual inquiry were used to inform the identification and analysis of potential behavioral barriers, detailed below.



Barrier 1: Researchers and recruiters may not acknowledge, address, or account for the deep-seated historical distrust Black individuals associate with medical research.

Consistent findings from our contextual inquiry center on the deep-seated distrust Black individuals associate with the medical system. These feelings

are based in historic and ongoing injustices, specifically in clinical research. The painful legacy of “hyper-experimentation on Black bodies” serves as a central barrier for enrollment of Black participants, informing their *mental models* of how clinical trials are or could be conducted (ONeal, 2020). In contrast, researchers are thinking about enrollment differently than these potential participants, prioritizing the rapid recruitment of diverse participants to ensure equitable access, and on meeting quotas in order to make the long awaited vaccine available during a period of dire need. In order to foster participant buy-in, researchers need to overcome this *illusion of transparency* to acknowledge distrust and actively work to mitigate it through multiple channels.

Barrier 2: Untrustworthy sources are endorsing a COVID-19 vaccine.

The Trump Administration has been pushing for a COVID vaccine in lieu of other public health measures since the beginning of the pandemic. The pressure the Administration has put on research entities, like the FDA, has made individuals wary of the efficacy of potential vaccines, and left them to fear that vaccine developments are reflective of a political agenda rather than scientific advancement. An interview with clinical researcher Florence Momplaisir, she highlighted this sentiment, stating “One of the

common themes is that people don't trust the vaccine. The main reason is white supremacy and the political environment and linkage to the Trump Administration. People feel that the vaccine is not for them." Interventions aimed at increasing enrollment among Black participants should focus on changing *mental models* around potential vaccines to mitigate *distrust*.

Barrier 3: Individuals may be unaware that trial participation is an option.

The COVID-19 pandemic has presented citizens with a unique opportunity to monitor vaccine development in real time. Given that this does not happen often, individuals may be unaware that scientists need individuals to participate in trials to ensure a vaccine is safe and effective. A lack of awareness surrounding the need for trial participants may be further exacerbated by the absence of a reliable centralized repository of information about COVID-19. Sources such as the CDC are no longer considered as reputable due to the constantly changing information citizens are being provided about COVID-19, and perceived role of political influence as detailed above. Additionally, researchers may be doing a poor job at advertising vaccine trials to potential participants. In order to recruit individuals, researchers and government bodies should make a concerted effort to increase the *salience* of vaccine trial enrollment.

Barrier 4: Weighing the benefits vs. risks of enrolling in the trial is taxing and confusing.

Information surrounding potential COVID-19 vaccines is confusing and contradictory, leaving some Black participants to their own devices to determine the relative safety of a vaccine as they consider their own participation in clinical trials. The many stressors that result from the pandemic limit the *cognitive bandwidth* individuals have available to make important decisions about enrolling in trials. To counter the side effects of *cognitive scarcity*, public health professionals and authority figures need to establish clarity on the purpose, process, and potential of the vaccine.



Barrier 5: There are logistical concerns and time constraints worth considering when participating in a clinical trial.

Participation in COVID-19 Phase 3 clinical trials creates unique challenges for the participants when considering the logistical elements of research, including longer visits lengths and study lengths. As trial length and the burden of participation increases, participants are more likely to consider the tradeoffs of participation with other elements of their daily life such as work, childcare, and more. As researchers work to recruit the necessary members of the Black community, they must ensure that participants are given proper information about the time commitment of these research studies. More importantly, trials need to be designed to reduce attrition where possible, through proper *logistical* planning.

Bottleneck 6: Enrollment may be impacted by knowing whether others are choosing to participate in the trial or not.

According to the *social norms theory*, human behavior and decision making is meaningfully influenced by the perception of the actions of others (Reid, 2010). When considering the diversity of enrollment in Phase 3 COVID-19 trials, it is imperative to take into account participants beliefs about peer involvement. In order to promote enrollment among Black community members, researchers need to acknowledge the importance of *social bias* and power of *conformity bias*, informing potential participants of others enrolling and pushing back on a hesitant status-quo.

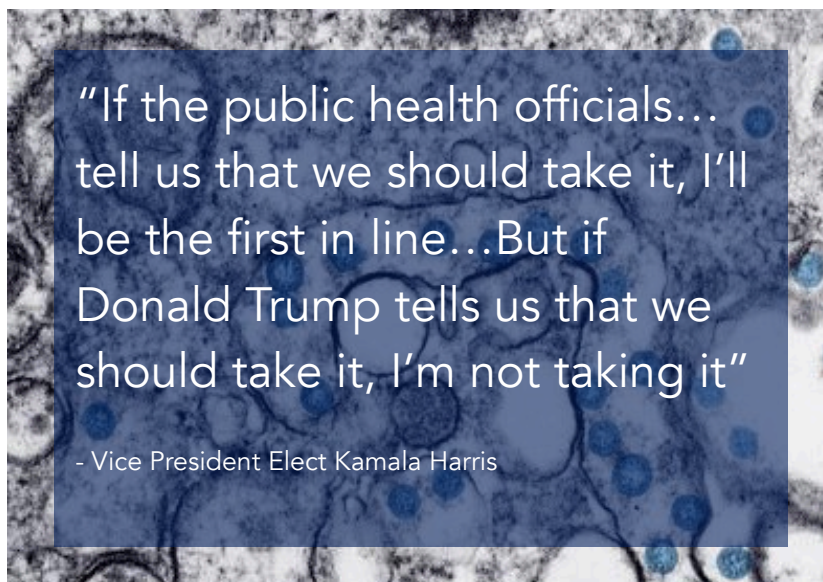
3 / Proposed Interventions

Together, these four interventions offer unique ways to target barriers of awareness, access, inadequate or confusing information, and trust in the vaccine trials. For a successful increase in the participation of Black community members in Phase 3 COVID-19 clinical trials, these barriers must be considered from a variety of viewpoints. It is imperative for research teams to take a multi-targeted approach, considering the diversity of both an individuals' psychological principles and relevance to specific barriers. For this reason, our team proposes each of these as stand-alone interventions, aimed at targeting overlapping populations within the same community. However, we

have also considered an integrative option that could allow for versions of these interventions to be adapted into a smart phone app or website format.

3.1 Town Hall / Ask Me Anything

One communication based intervention we consider is a series of virtual town halls that inform the community about ongoing vaccine progress on a recurring basis. Ideally, these town halls would occur weekly, monthly, or quarterly on a standardized day of the week and time. The frequency should be highest when gaining interest to accommodate people's schedules and information sharing of the event, simultaneously matching the rapidity of news related to the vaccine progress. The coordination of virtual meetings are at an all-time high in the face of the COVID-19 pandemic, widening the scope of those comfortable joining and including community members whose schedule would otherwise not permit an in-person meeting.



It is highly advantageous to utilize social norms that are already in place when rolling out an intervention. In this case, town halls are already an accepted form of community interaction and will not require any kind of new infrastructure. Rather, a town hall format empowers individuals to use comfortable channels to voice their own opinion

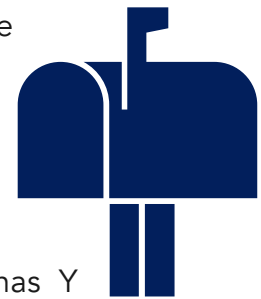
and influence vaccine development within their network. Importantly, town halls offer opportunities for community members to hear from *credible messengers* within their network, fostering greater trust in the process. Ask Me Anything (AMA) formats could be useful in allowing community members to hear from Black participants in the trials, and offer opportunities to “debunk” common myths, concerns, or confusion surrounding trial participation. This option can steer choice architecture change, refining choices for participation and increasing personal autonomy. Town halls can

directly mitigate the key barrier of individuals' lack of awareness that trial participation is an option by opening conversation and increasing visibility to enrollment steps.

There are several steps to consider when rolling out this intervention, namely the timing, frequency, and logistics of hosting such town halls. With the advice of community leaders, our team can identify a few key times in the week and stratify for attendance after a trial period. This will allow for people to learn about the town halls, while we gain data for the best times for each community to maximize attendance. Moving forward, we can simplify the times offered and hopefully ensure baseline engagement. We will also need a free, accessible platform that feels most comfortable for participants and potentially financial support to recruit scientists and clinicians to speak. With these plans in place and the help from community members, this intervention poses to be a highly successful form of communication.

3.2 Mailers

In order to address a number of these behavioral barriers, one communication intervention is to send out informational mailers about vaccine trials to members of the community. These mailers will include comparative statistics to other relevant communities depending on salient identity markers such as neighborhood or city. For example, “New York City has X trials enrollees, Philly only has Y enrollees.” Inspired by the the Milkman et al. (2018) flu vaccine study, mailers would also include a “date and time” field where participants could self-commit to attending an information session about trial participation. These self-commitment devices would not be sent back to any research team, instead they may be used as a continued reminder for the participants.



These mailers hold potential to promote transparency and mitigate the lack of vaccine trial awareness in the community, surmounting into a state of information asymmetry. Mailers can offer direct action items, such as information about aforementioned town halls, and validated information which can inform individuals of how to participate. Furthermore, these direct, actionable steps allow participants to make a plan, which

statistically increases the likelihood of following through on many desired actions such as flu vaccinations and voting behaviors.

Finally, human behavior is largely socially motivated and leveraging a comparison group such as other cities or zip codes should promote increased enrollment. Although this intervention is cheap and relatively easy to implement, our team is cognizant the effect size may not be substantial. Similarly, the effect of such an intervention may not hold up over an extended period of time, which is important to consider if vaccine trials will continue for an extended period of time. However, mailers do allow us to reach members of the population that may be averse to receiving information electronically, such as the elderly. As such, the potential outreach of this intervention and relatively low financial burden seems to offset questions of efficacy on an individual level.

3.3 Community Influencers

Our third intervention designed to increase and improve communication leverages local, known community influencers such as corner store and bodega employees. These employees hold a prominent, regular, and visible place in society. Additionally, they are not subject to the same closures as other stores throughout the pandemic, and represent less of a polarized role than perhaps a medical professional, even serving as credible messengers. Using similar methodology from the Buttenheim et al. (2019) Chagas bug spraying t-shirt intervention, branded masks could be worn at these local corner stores with COVID-19 trial participation information. As with the town hall intervention, using community influencers increases the visibility and awareness of trials while promoting factual information from trusted sources. It also increases the perception of enrollment and activity in trials locally, which pulls at a person's innate tendency to align with social norms.



By showing a community influencer's willingness for and endorsement of COVID-19 vaccine trials, more people may be encouraged to participate. This allows for a shift in one's mental model, which may otherwise have painted the vaccine as forced and pushed by untrustworthy sources such as mass

media and the Trump administration. In a time where the validity of science is under attack, a grassroots intervention leveraging community beliefs and trusted faces may open the door for underrepresented groups to participate regularly.

While productive intentions and behavioral principles provide the grounds for this intervention, there is a notable challenge in gaining community influencer support. There will need to be designated trial ambassadors to answer the influencer's questions should they not understand or feel positively toward the vaccine trials. However, this education and dialogue must not verge onto coercive, making the question of reimbursement salient. Our team will also require funding for the promotional materials and educational resources needed at each site. Furthermore, this intervention is designed with a bias toward urban layouts and must be adapted for any rural settings.



3.4 Microsites / Trial-to-go

Our fourth intervention targets logistical barriers that may currently be prohibiting individuals from participating in trials. We propose a partnership between research and health brands such as CVS or Walgreens to promote trial enrollment, via both in-store and digital channels. The intervention would link trial enrollment to existing health behaviors including, but not limited to flu-shots, pharmacy purchases, medication reminders, and include local community influencers in-store. Additionally, research teams could establish temporary vaccine trial sites at local community centers, similar to a mobile blood bank. Both of these interventions lower the barrier to access and put the trial at the forefront of people's minds, ultimately resulting in both awareness and enrollment.

While many people are not comfortable with physicians, much less vaccine trial researchers, they are familiar with their local pharmacy. Using credible messengers and endorsements from brands such as CVS and Walgreens will allow us to leverage a participant's existing relationship with such pharmacies to increase enrollment. Additionally, bundling tasks allows for participants to link enrollment with existing behaviors such as pharmacy pick ups. This reduces hassle factors, and instead meets people where they are. Finally, using popular sites will utilize social norms further by

allowing participants to see other community members enrolling or expressing interest in the trial. Together it validates and heightens the trial's visibility.

Despite the clear benefits in a more convenient pop-up site, the barriers in this intervention could prove fatal to the goal. Firstly, our team must determine the legality of such a pop-up site and whether multiple companies could promote in a location or one trial will get a monopoly per brand. Additionally, we must determine the willingness of big brands to participate and volunteer both funds and resources. This may be broached on a local level, but it's possible the national scale of these brands could alter the potential of local uptake. From a logistical standpoint, the decrease of in-store shopping during COVID-19 could reduce foot traffic and lessen the impact of this intervention. However, should the production and legality of this intervention prove viable, using the existing infrastructure of branded sites could function as an impactful step to improving trial access.

4 / Impact

How can we encourage more Black participants to enroll in COVID-19 vaccine trials? This question sparks discussion on many possible underlying factors as to why there is a shortage of participants in a group that is so disproportionately burdened by the pandemic. We focused our research on three main channels: discussions with members of the target population, interviews with

Philadelphia medical professionals, and review of the existing literature. Our research resulted in a few key takeaways which influenced our response to the above question.




Discussions with the target population revealed three main factors, some of which reappeared as common themes from other sources of information. Ensuring that vaccine allocation was equitable and timely was one of the main concerns. Clear and consistent recruitment messaging is a concept that appeared but also reappeared throughout our research. Mistrust of both the medical community and the current

political climate emerged as another consistent theme. Members of the Black community realize their disproportionate risk for the virus, but feel uncomfortable with past vaccination strategies heightened by the current political climate.

Interviews with medical professionals mostly lead to the same conclusions as with the target population. This indicates that there is little to no dissonance between the two, there is a general desire for professionals to mitigate the effects of COVID-19 on the Black community and a similar desire for the Black community to embrace vaccination uptake, albeit under proper circumstances. However, medical professionals realize that the main barriers to achieving this goal require consistent and clear communication efforts such as proper channels, continuing education, appropriate delivery; but also realistic uptake goals. As we continue to develop vaccines through clinical trials, health professionals understand that continued efforts to recruit Black participants will require effort on multiple fronts by attacking the barriers we have mentioned above.

Our final sources of information came from a broad literature review. This included opinion based sources, academic sources, and news sources. Each realm gave validated findings surrounding the mistrust of medical and political figures among the Black community. However, these sources also gave us insight into how widespread this concept is among the Black, and even minority community, worldwide. The compilation of personal discussions with the target population, interviews with medical professionals, and literature review provided meaningful data to inform our intervention design and strategy.

Ultimately, we narrowed down the answer to the question to the following barriers: lack of acknowledgement of mistrust, endorsement of treatment from untrustworthy resources, lack of education on trial participation, the taxing nature of weighing risks



“Transparency is key. Any intervention aimed at enrolling Black participants has to encourage transparency throughout the process”

- Community member & recovered COVID-19 patient

and benefits of trial participation, logistical concerns, and lack of transparency behind peer behavior. The combination of these barriers and their associated underlying cognitive biases lead to our proposed interventions. Mailers as a staple of the behavioral intervention suite of interventions, are useful for addressing populations that may lack technology resources and/or skills. Town halls branded as “Ask Me Anything” (AMA) could serve as a platform for community input on clinical trials. Collaboration with community influencers, and microsites to make vaccine uptake more visible and accessible for the Black communities.

We recognize the challenges associated with the chosen interventions. However, we believe they will pave the way for a great future with COVID-19 vaccine acceptance in the Black community in Philadelphia, and potentially beyond. With proper planning and guidance this could give way to an abundance of opportunities for further improvement via future developments such as a digital app to tie together all of the interventions for more impactful behavior change.

5 / References

Ahaghotu C, Tyler R, Sartor O. African American Participation in Oncology Clinical Trials- Focus on Prostate Cancer: Implications, Barriers, and Potential Solutions. *Clinical Genitourinary Cancer*. 2016; 14(2):105-116. <https://doi.org/10.1016/j.clgc.2015.12.003>

Aslan M, Wanamaker M, Tuskegee and the Health of Black Men. *The Quarterly Journal of Economics*. 2018; 133(1):407-455, <https://doi.org/10.1093/qje/qjx029>

Borno HT, Zhang S, Gomez S. COVID-19 disparities: An urgent call for race reporting and representation in clinical research. *Contemp Clin Trials Commun*. 2020;19:100630. Published 2020 Jul 30. doi:10.1016/j.conctc.2020.100630

Buttenheim, A.M., Levy, M.Z., Castillo-Neyra, R. et al. A behavioral design approach to improving a Chagas disease vector control campaign in Peru. *BMC Public Health* 19, 1272 (2019). <https://doi.org/10.1186/s12889-019-7525-3>

Chastain DB, Osae SP, Henao- Martinex AF, Franco-Paredes C, et al. Racial Disproportionality in Covid Clinical Trials. *The New England Journal of Medicine*. 2020; 383:e59. doi:10.1056/NEJMp2021971

Corbie-Smith G, Thomas SB, St George DM. Distrust, race, and research. *Arch Intern Med*. 2002 Nov 25;162(21):2458-63. doi: 10.1001/archinte.162.21.2458. PMID: 12437405.

Legal Monitor Worldwide. COVID Vaccine Trials Move Fast But They're Slow To Recruit Black Volunteers. 2020. Retrieved from: https://link.gale.com/apps/doc/A635784961/ITOF?u=upenn_main&sid=ITOF&xid=48fc2e31

Milkman KL, Beshears J, Choi JJ, Laibson D, Madrian BC. Using implementation intentions prompts to enhance influenza vaccination rates. *Proc Natl Acad Sci U S A*. 2011 Jun 28;108(26):10415-20. doi: 10.1073/pnas.1103170108.

National Institutes of Health, NOT-OD-20-031: Notice of NIH's Interest in Diversity. 2019. Retrieved from <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html>

ONeal L. (2020, October 15). Half of Black adults say they won't take a coronavirus vaccine, *The Undeclared*. Retrieved from: <https://theundefeated.com/features/half-of->

black-adults-say-they-wont-take-a-coronavirus-vaccine/

Philadelphia Department of Health. Coronavirus Disease 2019 (COVID-19) Testing and data: City of Philadelphia COVID-19 Overview. 2020. Retrieved from: <https://www.phila.gov/programs/coronavirus-disease-2019-covid-19/testing-and-data/#/>

Reid AE, Cialdini RB, & Aiken LS (2011). *Social norms and health behavior*. In A. Steptoe, K. Freedland, J. R. Jennings, M. M. Llabre, S. B. Manuck, & E. J. Susman (Eds.), *Handbook of behavioral medicine: Methods and applications* (p. 263–274). Springer Science + Business Media.

Scharff DP, Mathews KJ, Jackson P, Hoffsuemmer J, Martin E, Edwards D. More than Tuskegee: understanding mistrust about research participation. *J Health Care Poor Underserved*. 2010;21(3):879-897. doi:10.1353/hpu.0.0323

Tai DBG, Shah A, Doubeni CA, Sia IG, Wieland ML. The Disproportionate Impact of COVID-19 on Racial and Ethnic Minorities in the United States. *Clinical Infectious Diseases*. 2020. <https://doi.org/10.1093/cid/ciaa815>