Ethical Inclusion of Health Care Workers in Covid-19 Research

Holly Fernandez Lynch, Dawn Lundin, and Emma A. Meagher

ABSTRACT Employees are often considered a vulnerable research population due to concerns about consent and confidentiality, but there is insufficient guidance regarding their ethical inclusion in research. In the context of Covid-19, frontline health care workers comprise a particularly relevant research population in light of their risks of viral exposure and psychological strain, among other factors. They may therefore be targeted for research conducted at their place of employment and benefit from participating in such research. Beyond Covid-19, there are other circumstances in which health care workers may be considered for inclusion in research conducted by or with the involvement of their colleagues and employers. As investigators, sponsors, institutional review boards, and others assess the ethical permissibility of these scenarios, as well as relevant protections, we recommend systematic consideration of social and scientific value, validity, fairness, risks and benefits, voluntary consent, respect, and independent review. There is often good reason to specifically target health care workers for inclusion in Covid-19 research (beyond convenience), and they should not be excluded from research offering the prospect of direct benefit. However, additional safeguards may be necessary in employer-based research to avoid scientific bias, promote voluntariness, and solicit stakeholder input. Research personnel should be permitted to enroll in their own Covid-19 studies only when participation offers them the prospect of unique benefits.

KEYWORDS Covid-19, human subjects research, human research ethics, institutional review boards, employees, health care workers, research personnel

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Because frontline health care workers face heightened risks of exposure to the novel coronavirus SARS-CoV-2,[1] they have been sought as research participants in a large number of clinical trials of chemical prophylaxis and vaccines, diagnostic test validation studies, and prospective observational studies of exposure and infection, often conducted, supported, or endorsed by their colleagues and employers.[2] In addition, if health care workers become sick with Covid-19, they may receive care at their place of employment, where they are likely to be presented with options to participate in research given the dearth of proven treatment options.[3]

Institutional review boards (IRBs) often consider employees to be a vulnerable research population,[4] largely due to concerns about employees' ability to provide voluntary consent and challenges related to their privacy and the confidentiality of their personal information. IRBs—and other stakeholders, including investigators and sponsors—may therefore struggle with how to appropriately assess Covid-19 studies that will intentionally or incidentally include health care workers as research participants at their places of employment. Although special protections are often in order, as with any vulnerable population, it is essential to avoid overprotection through blanket approaches that fail to consider relevant circumstances and available safeguards.[5] During a pandemic, and also in other contexts, health care workers are often the population of inference for research, as well as members of broader populations of

patients that may be expected to benefit from research participation. Applying the widely endorsed framework for what makes clinical research ethical that was developed by Emanuel, Wendler, and Grady,[6] we offer guidance about when it is appropriate to include health care workers in Covid-19 research conducted by their colleagues and employers, as well as how their interests can best be protected under these conditions.

Note that we do not intend to conceptualize employees in the strictly legal sense (as opposed to independent contractors or volunteers, for example), especially since clinical practitioners sometimes are not true employees of the institutions in which they work. Instead, we use the term *employee* as a broader designation intended to refer to those in a working relationship with the individuals or entities involved in conducting the research in question or otherwise supporting or endorsing that research. We direct our attention primarily to clinical staff, a population that may be uniquely targeted for certain types of research, that may have a unique interest in enrollment, and that may have a unique understanding of research design, risks, and benefits, in contrast to nonclinical staff. However, parts of the analysis are also relevant to the inclusion of other types of employees in health care settings, some of whom may also be described as frontline workers, such as patient transport teams, food workers, maintenance and janitorial staff, and others, as well as to research involving employees in non-health care settings. We also consider special issues that arise with regard to the inclusion of research personnel as study participants. We focus on Covid-19 research in part because of its urgency and because of the frequency with which these workplace-related ethical questions have arisen in the context of the pandemic. However, the analysis can help guide the enrollment of employees in both pandemic and nonpandemic circumstances. Finally, although we focus on the U.S. context, our ethical analysis has broader relevance, provided that adequate care is taken to comply with local regulatory obligations and to account for local circumstances.

REGULATORY BACKGROUND

Whereas federally funded research with prisoners,[7] pregnant women, fetuses, neonates,[8] and children[9] is subject to distinct regulatory requirements and protections, U.S. regulations do not treat employees as a distinct category of research participants or even speak directly to their inclusion in research. However, the Federal Policy for the Protection of Human Subjects (the Common Rule) requires attention to the "special problems of research that involves a category of subjects who may be vulnerable to coercion or undue influence."[10] This language reflects a recent update to be more specific about the type of vulnerability that matters, while the U.S. Food and Drug Administration's rules still use more general language, calling on IRBs to be particularly "cognizant of the special problems of research involving vulnerable populations."[11] Both sets of regulations then provide nonexhaustive examples of vulnerable groups, including individuals with impaired decision-making capacity and economically or educationally disadvantaged persons, but making no mention of employees. They also both require "adequate provisions" to protect participant privacy and confidentiality.

Although the regulations offer no explicit definition of vulnerability, both voluntariness and confidentiality raise heightened concerns with regard to employees approached about research participation in their workplace. As Resnik has described in detail, employees may worry about adverse employment consequences for refusal or anticipate special employment benefits from enrollment; this is true even if they otherwise exercise substantial independence and discretion in their work, as is true for many health care workers, since they may fear loss of contracts and privileges, for example. If they enroll, they may also have increased confidentiality concerns based on the possibility that coworkers, superiors, and employers would have access to their personal health information or other sensitive matters.[12]

It is precisely because the basic protections provided for all research participants may be inadequate for employee participants that they are properly understood as a vulnerable research population.[13] Indeed, guidance from U.S. regulators acknowledges that investigators and IRBs need to be cautious about enrolling employees, although they make no specific suggestions as to what additional protections would be appropriate or when it may be best to exclude employees from research altogether.[14] More detail is provided about safeguarding students in research, a population that regulators describe as analogous.[15] For example, a now archived *IRB Guidebook* proposed advertising for student sub-

jects through general notices so that they may express their interest spontaneously, rather than recruiting eligible individuals directly, which may result in perceived pressure to enroll. It also suggested that IRBs consider adding a student member or otherwise consulting with students for further perspective.[16] We note that although students are traditionally not characterized as employees, to the extent that they are engaged in clinical care activities as medical and nursing students, for example, they may fall within the types of health care workers that could be considered for research inclusion, creating vulnerability across multiple axes for them as both students and workers.

In the absence of clear guidance from regulators, IRBs and study sponsors take various approaches to including employees in and excluding them from research.[17] The fact that best practices have yet to emerge is especially problematic in the context of a pandemic in which the question of whether and how to include health care workers as participants in research conducted at their workplaces is pressing.

ETHICAL CONSIDERATIONS

In a 2000 article that has become one of the foundational texts of research ethics, Emanuel, Wendler, and Grady expanded the basic ethical principles for research articulated in *The Belmont Report*[18]—respect for persons, beneficence, and justice—into a framework for evaluating the ethical permissibility of clinical research based on several requirements.[19] Applying this framework to Covid-19 research enrolling health care workers makes it clear that this can be done ethically with appropriate safeguards (see table 1).

Value, validity, and fairness. The first criterion for ethical clinical research is social or scientific value, meaning that no research should be allowed to proceed unless it will meaningfully contribute to generalizable knowledge that can improve health and well-being.[20] This relates to the second criterion of scientific validity, since research will lack value if it is unable to produce reliable and valid data, as well as the third criterion of fair selection of participants, since participant selection should be driven by scientific justifications rather than mere convenience or exploitation of vulnerability.[21]

Based on these criteria, Covid-19 research should intentionally target health care workers for enrollment only when doing so can contribute to answering an important scientific question of particular relevance to health care workers. This could be true of a range of research, including both interventional and observational studies, as well as studies involving minimal and greater than minimal risk. For example, there is an urgent need to develop rapid point-of-care SARS-CoV-2 diagnostics and prophylaxis for health care workers and the general population. Higher anticipated levels of viral exposure among frontline health care workers will offer a strong opportunity to test both, potentially enabling research questions to be answered more quickly and with fewer participants compared to relying on recruitment of populations at lower risk of exposure, in whom the burden and risk associated with attending study visits would also be greater. Similar justifications support conducting studies evaluating antibody testing in frontline health care workers due to their risks of exposure and the potential value of such tests in determining who can treat Covid-19 patients most safely. Studies of psychological strain experienced by health care workers caring for Covid-19 patients, and of interventions to address that strain, also have clear reason to target this population. In contrast, it would not make sense to target health care workers for a SARS-CoV-2 vaccine challenge study, for example, given the importance of limiting viral exposure exclusively to the challenge rather than that which might occur naturally "in the field."

> Even when the inclusion or exclusion of health care workers will not have any special influence on the risks and benefits of Covid-19 research, if these workers might experience direct benefit from participation, their exclusion from studies conducted at their workplace should be a last resort.

Table 1.
Ethical Considerations for Including Health Care Workers in Workplace-Based Covid-19 Research

Criterion	*Analysis*	*Safeguard*
Social or scientific value	High risks of infection make health care workers an important population for inclusion in some types of Covid-19 research.	Target health care workers only when doing so will meaningfully contribute to answering important scientific questions.
Scientific validity	Including health care workers at work could bias study data.	Discourage participants from "comparing notes" or self-prescribing. Avoid exposing participants to interim findings.
Fair participant selection	There may be good reasons to target health care workers for inclusion. Incidental inclusion of health care workers avoids concerns about exploitation.	Do not exclude health care workers from employer-based studies offering the prospect of direct benefit when other safeguards are possible.
Reasonable risks and benefits	Including health care workers can maximize benefit.	Do not exclude health care workers from employer-based studies offering the prospect of direct benefit when other safeguards are possible.

These examples suggest that it sometimes can be reasonable, fair, and scientifically valid to target health care workers for Covid-19 research conducted at their workplace, despite their potential vulnerability in this setting, provided that the research is responsive to the group's needs and that selecting a different population would likely be inferior.[22] When health care workers are not specifically targeted for inclusion in Covid-19 research but, rather, incidentally enrolled alongside other types of participants as scientifically appropriate, there is even less reason for concern that their vulnerabilities are being exploited or that they will bear an unfair share of research burden and risk.

Although there often will be good reason for including health care workers in employer-based Covid-19 research, considering and addressing any heightened opportunity for bias that could affect the criterion of scientific validity is also important. Especially in studies involving healthy participants (rather than treatment studies in which Covid-19 patients will be isolated and potentially quite sick), employee participants may be more likely than nonemployee participants to be exposed to information in the workplace that might influence their behavior.[23] For example, as a result of their proximity to other study participants who are also employees, they may glean insight regarding individual or aggregate adverse reactions or have more opportunity to compare their study drug to that of others in a way that could lead to unblinding.[24] To address these concerns, employee-participants should be counseled against discussing specifics of their study participation with one another or otherwise accessing study records,[25] and research personnel should exercise care when discussing or presenting interim findings in venues accessible to employee-participants, such as grand rounds. In addition, when health care workers enrolled in research can access a study intervention outside a trial, such as dexamethasone or other drugs being used off-label for Covid-19 or other products available through emergency use authorization, they should be counseled against self-prescribing. Similar precautions may be appropriate for other types of participants as well,[26] who may access information on the internet, connect with other participants, or request off-label drugs from their nonstudy prescribers, but these concerns are each heightened for certain types of employee-participants.

Risks and benefits. The fourth criterion for ethical research is that it must have a favorable risk-benefit

ratio, with risks minimized and reasonable in relation to potential benefits to individual participants and society.[27] This relates to the criterion of fair participant selection, since fairness calls for not only avoiding the imposition of disproportionate risks on any population but also making sure not to exclude certain populations from the benefits of research participation without good reason.

For Covid-19 prophylaxis research, including frontline health care workers can be viewed as a way to minimize risks, since their potentially heightened background risk of viral exposure reduces the marginal risk of study participation compared to the risk participation poses to other healthy individuals. Including health care workers can also maximize benefits when doing so will help answer research questions more quickly than other approaches will, as noted above. Moreover, if the experimental intervention turns out to be safe and effective, whether for Covid-19 prevention or treatment, including health care workers can maximize benefits by enhancing their capacity (i.e., while healthy) to provide care to more patients in need.[28]

Even when the inclusion or exclusion of health care workers will not have any special influence on the risks and benefits of Covid-19 research, in cases where these workers might experience direct benefit from study participation, their exclusion from studies conducted at their workplace should be a last resort used only when other safeguards are inadequate; this principle should apply whenever employees are eligible for research that offers the prospect of direct benefit. Although the purpose of research is to produce generalizable knowledge to benefit future patients and it is important not to fall prey to assumptions that experimental interventions will be beneficial,[29] especially in the face of a public health emergency and the absence of strong clinical interventions, the opportunity to receive a promising experimental product while contributing socially valuable data may be the best available alternative. Withholding that option on the basis of employment status—especially from those, such as health care workers, who are at heightened risk precisely because of that status—should be avoided if possible.

Beyond potential benefit, it is important to consider the possibility that health care workers may be harmed by participating in some types of Covid-19 research, including in ways that would take them away from their essential patient care or research roles.[30] However, this needs to be balanced against the likelihood of the same possible outcomes if they were to become infected with or die from Covid-19. Overall, the risks and benefits of including health care workers in Covid-19 research will often be reasonable but must be assessed on a case-by-case basis.

Voluntary informed consent. The fifth criterion for ethical research, subject to certain exceptions, is valid informed consent,[31] including adequate disclosure of material information, comprehension, and voluntariness.[32]

In some ways, enrolling health care workers in Covid-19 research may improve the quality of consent comprehension against a background of substantial misinformation and hype about pandemic interventions. By virtue of their education, training, and experience, health care workers are also among the best suited to understand the uncertainties and risks associated with research participation, the value of rigorous study design, including randomization and blinding, and the importance of completing study participation, as well as the caveats that will often be associated with newly reported research data. It is not the case, of course, that others are incapable of understanding these details, but it is likely that the degree of understanding among some types of health care workers will be more consistent.

However, as noted above, there are also concerns about voluntariness when enrolling employees, who—as a result of their employment status—may feel real or perceived pressure to participate in research conducted at their workplace. Importantly, these concerns apply regardless of research risk; voluntary consent is often needed even for low-risk research. To minimize these concerns, rather than specifically approaching individuals about participation, it is usually best to use general recruitment messaging to all eligible employees that encourages them to express interest at their own initiative. In addition, recruitment by anyone in the employee's supervisory hierarchy or immediate working group should be avoided.[33] Although all prospective participants must be assured that study participation is voluntary, employees should be specifically assured that there will be no adverse employment consequences, nor any employment benefits, based on their decision about re-

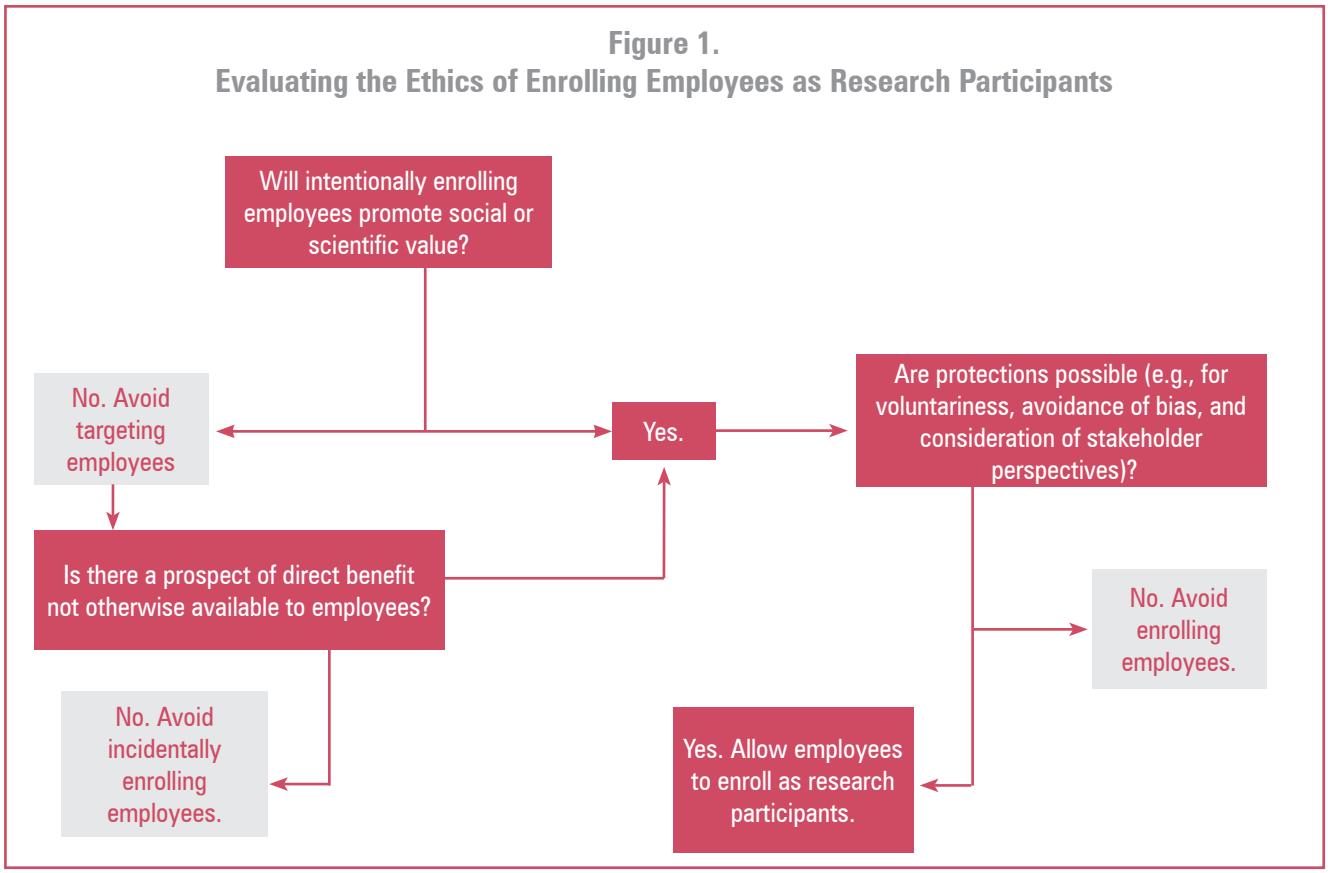
search participation.[34] Ideally, the fact of an employee's participation or refusal could be kept confidential from anyone in a position to render employment decisions, although this will not always be possible.

In the context of a pandemic in which there have been shortages of personal protective equipment[35] and concerns about inadequate availability of supportive care interventions, as well as a dearth of proven prophylaxis and treatment options,[36] there may be some concern that the prospect of direct benefit from research participation at work will unduly influence health care workers' decisions to enroll. However, we must distinguish between unfortunate background circumstances and undue influence: the lack of good alternatives does not necessarily make research participation unreasonable or involuntary.[37] To the contrary, many health care workers are likely to have a strong voluntary desire to participate in Covid-19 protocols, for both altruistic reasons and based on a determination that enrollment is their best available alternative.

Respect. The sixth criterion for ethical research is respect for participants, including adequate confidentiality protections.[38] Although this may be a particular worry for health care workers and other employees, who might fear that their colleagues and employers will have or seek access to personal information collected for research purposes, traditional research privacy protections should suffice to mitigate this concern, especially if emphasized during the consent process. As for any research study, data gathered from employee participants should be deidentified when possible, provided to as few personnel as possible, and shared only in ways that minimize concerns about embarrassment, stigma, or discrimination,[39] with clear consequences and strict penalties for those who inappropriately access participant data. Participants should be assured that research data will not be used to make positive or negative employment decisions regarding performance or incentives. To the extent that health care workers suffering from Covid-19 seek medical care at their own institution, their participation in research is unlikely to raise any heightened confidentiality concerns.

Independent review. The seventh and final criterion for ethical research is independent review by an appropriately constituted group of experts, such as an IRB.[40] IRBs located within research institutions often include

Figure 1.
Evaluating the Ethics of Enrolling Employees as Research Participants



employees from that institution, including health care workers, although research may also be reviewed by commercial IRBs without that particular perspective. Even when health care workers drawn from the institution's employees are part of a board's membership, however, they may not represent the specific population of health care workers being considered for study enrollment at the institution. Given the potential ethical concerns, both real and perceived, raised by inclusion of employees in research, IRBs and investigators should consider means of soliciting feedback from the types of employees who might be included in proposed Covid-19 studies; focus groups, for example, could provide a forum for concerns and ideas about how those concerns might be resolved.

Research personnel. Although our main focus is on enrollment of health care workers in Covid-19 research conducted at their place of employment, one further question is whether any of the ethical considerations differ regarding the potential enrollment of employees who are also study personnel, including investigators and research coordinators.[41] There is a long history of self-experimentation in medical research,[42] and the willingness of research personnel to expose themselves to the interventions under investigation can signal confidence—or overconfidence—that the risks and potential benefits are reasonable for others to undertake as well. However, there are also pitfalls in being too close to one's research, such as a lack of objectivity in data reporting, recording, and analysis; distorted perspectives regarding adverse events; or viewing promising signals as more substantial than is truly warranted. Depending on the rates of enrollment among research personnel, there is also the possibility that including them as participants will distract from efficient study conduct, as they are pulled away for their own study visits and activities or if they experience serious adverse events.[43]

All these reasons suggest that employers should adopt a presumption against allowing research personnel to enroll in their own research projects. Considering the requirements for ethical research, there is no unique scientific benefit to including them, in contrast to health care workers specifically, and doing so raises important concerns for study validity. Moreover, it is not clear that inclusion of study personnel as participants would meaningfully address distrust in Covid-19 research stemming from health inequities, social injustice, and racism.[44] Pandemic safeguards to reduce staffing to essential personnel only can result in investigators having to play expanded clinical care, research, and administrative roles, which, in turn, can lead to risks associated with low employee bandwidth should investigators also seek to enroll in their own studies.

Nonetheless, when Covid-19 protocols offer the prospect of direct benefit, excluding those who would otherwise be eligible for study participation but who also play a role in conducting the research would demand a substantial sacrifice. Other protections should be considered first before precluding the enrollment of research personnel in this context.

CONCLUSION

In general, enrolling employees in research deserves special attention due to concerns about pressure to participate, confidentiality, and bias (see figure 1). However, there are often compelling reasons to allow health care workers to participate in Covid-19 studies conducted at their workplace (and all employees to enroll in research in other contexts), so long as appropriate safeguards are in place. Investigators should be expected to provide, and IRBs expected to confirm, specific justifications for the inclusion of employees in research and specific details about how ethical concerns will be overcome. Both parties should be guided by the seven requirements for ethical research.

Including health care workers in Covid-19 research conducted, supported, or endorsed by their colleagues and employers may sometimes promote social and scientific value. In addition, their inclusion will often be fair rather than exploitative, and concerns about scientific validity can be managed. When Covid-19 research offers the prospect of direct benefit to participants, health care workers generally should not be excluded, and this potential benefit should not be viewed as invalidating informed consent even when there are no good alternatives to enrollment. Steps should be taken, however, to make sure that health care workers clearly understand that their participation will have no impact on their employment status. Traditional research confidentiality protections should suffice to protect the privacy interests of employee participants, although it may also be appropriate to solicit the input of health care

workers about their inclusion in employment-based Covid-19 research to make sure their broader interests and concerns are adequately addressed. Research personnel should be permitted to enroll in their own Covid-19 studies only when participation offers them the prospect of unique benefits.

Given the number of studies enrolling health care workers, the Covid-19 pandemic provides an important opportunity to address the lack of clear standards for the ethical inclusion of employees in research, and the inclusion of health care workers in particular. The well-established framework for what makes clinical research ethical helps to resolve that lack of clarity in ways that also will be relevant beyond the pandemic. ♦

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