The Duty to Rescue and Investigators’ Obligations

The duty to rescue is a highly plausible and powerful ethical principle. It requires agents to assist others in extreme need in cases where doing so (1) does not conflict with some weighty moral aim; (2) requires little personal sacrifice; and (3) is likely to significantly benefit the recipients.[[1]](#footnote-1) As a *general obligation*, it binds all persons simply qua persons, and it is owed to all persons simply qua persons. Clinical investigators working in low-income countries frequently encounter sick or destitute people to whom they might possess a duty to rescue. Investigators may often ask themselves, *what can I do, what should I do, to help?* Such investigators often help people in the future by carrying out their research projects; research in resource-poor settings often concerns disease interventions that promise to improve or save future lives. But research and rescue are distinct aims: research aims at prevention or future intervention, while rescue responds to immediate, urgent needs. Investigators who encounter people in great need may still want to know if they should take action to meet rescue needs now.

It’s no surprise that ethicists have invoked the duty to rescue to define and justify investigators’ obligations to subjects in low-income countries. Jennifer S. Hawkins appeals to this duty to argue that investigators should not conduct placebo-controlled trials except in cases where doing so is necessary to serve a weighty moral aim; the duty to rescue requires that subjects receive an active intervention.[[2]](#footnote-2) Maria W. Merritt appeals to the duty to rescue to define and justify some of the ancillary care obligations investigators possess to their subjects.[[3]](#footnote-3) What both ethicists have in common is the view that the general duty to rescue generates *specific* investigator obligations toward research subjects in resource-poor settings. Further, both Hawkins and Merritt take their conclusions to be *policy-relevant*, that is, to be normative for the construction of regulations to govern clinical research in low-income countries.[[4]](#footnote-4)

In this paper, we investigate the implications of the duty to rescue for investigators conducting research in low-income countries. We argue that Hawkins and Merritt are wrong to think – to the extent that they do so – that the individual duty to rescue supports policy relevant, specific obligations such as standard of care or ancillary care obligations. We argue first that the argumentative strategy that Hawkins and Merritt would seem to be committed to faces two significant problems. First, it fails to explain why investigators possess obligations to research participants in particular. The problem here lies in the attempt to derive *special obligations* – i.e. obligations investigators owe *to specific persons*, in this case researchparticipants – from an obligation they possess *to all persons* – i.e. the duty to rescue. Second, Hawkins and Merritt’s strategy fails to recognize the normative significance of the *institutional context* within which investigators work. Hawkins and Merritt acknowledge that the duty to rescue applies to investigators simply qua persons;[[5]](#footnote-5) however in spelling out its implications, they understand investigators as institutional actors with their sponsor’s resources at their disposal.

We propose instead an alternative account of the duty to rescue and its implications for the conduct of clinical research in low-income settings. We distinguish between the *personal* duty to rescue – i.e. the duty to rescue individuals possess qua persons – and the *institutional* duty to rescue. By an institutional duty to rescue, we mean a duty to rescue that is held by a collective agent, whether a state or corporation, that can be inherited by its representatives or proxies.[[6]](#footnote-6) We argue that high-income states possess an institutional duty to rescue, and this implies that states should require their research agencies and investigators to use the public resources at their disposal to meet the needs of people in low-income countries when doing so (1) does not interfere with their research projects; and (2) imposes minimal costs on the agency.

By appealing to states’ institutional duty to rescue in this way, we resolve the second problem with Hawkins and Merritt’s argumentative strategy – their failure to recognize the normative significance of the institutional context of investigators. However, we do not think that the first problem we identify above—the derivation of a special obligation from a general one—can or should be resolved. We argue that neither the personal nor the institutional duty to rescue implies that investigators possess research specific obligations, such as standard of care or ancillary care obligations, as the best ways of discharging their duties. Instead, the specific implications of these duties depend on the circumstances within which investigators conduct their research. As such, the duty to rescue cannot provide the basis for a system of highly-specified rules and regulations governing clinical research across varying contexts. We caution against invoking the duty to rescue to argue broadly for specific policy-relevant investigator duties.

In Section 1, we outline Hawkins and Merritt’s views about specific researcher obligations derived from the duty to rescue. In Sections 2 and 3, we discuss the first problem with Hawkins and Merritt’s strategy, arguing that their accounts of specific researcher obligations fail; the individual duty to rescue cannot support specific, policy-relevant researcher requirements. In Section 4, we consider an alternative interpretation of researcher duties to rescue, according to which such duties are best understood to be professional duties. In Section 5, we discuss the second problem with Hawkins and Merritt’s strategy, namely, the failure to recognize the normative significance of the institutional context within which investigators work. In Section 6, we develop our account of the institutional duty to rescue and explore its implications for the conduct of research in low-income countries.

1 The Duty to Rescue and the Obligations of Investigators

The duty to rescue is most intuitively generated in a personal encounter with another person whose desperate need arises because of a unique emergency. Peter Singer’s Shallow Pond is emblematic.[[7]](#footnote-7) If a person encounters a child at risk of drowning in a shallow pond, she is morally required to ensure that the child is rescued, assuming minimal cost to herself. But much debate surrounds the scope of the duty—the range of cases in which it is applicable. For example, even if we only have a duty to assist others in extreme need in cases where doing so (1) does not conflict with some weighty moral aim; (2) requires little personal sacrifice; and (3) is likely to significantly benefit the recipients, these conditions could be fulfilled by a vast array of cases. We might have extensive obligations to meet the needs of the poor and sick throughout the world even though we do not personally encounter these people and their needs are the result of chronic social problems. Whether the duty to rescue should be limited to the narrow range of cases—those of unique, emergency encounters—or whether it cannot be so limited without drawing a morally arbitrary line is a matter of deep controversy.[[8]](#footnote-8)

Hawkins and Merritt seem to assume a narrow scope duty to rescue. Investigators incur duties to rescue research participants when they go to low-income countries, directly encountering their need. Though we do not defend the narrow duty to rescue, we will make our arguments on their terms. Our concerns about the misapplication of the duty to rescue to explain researcher obligations apply to the narrow conception of the duty. If a “wide scope” duty is most defensible, our concerns are magnified, as will become clear below.

As both Hawkins and Merritt note, investigators conducting research in low-income countries often encounter people in extreme need who are unlikely to be helped by local institutions. Merritt takes this as a basis for defining and justifying *at least some* of investigators’ ancillary care obligations to research subjects.[[9]](#footnote-9) [[10]](#footnote-10) In cases where subjects are in extreme need – e.g. are malnourished or suffering from life-threatening or seriously debilitating diseases – and are unlikely to receive help from the local health care system, investigators have a duty to provide them with the care they need, provided that they can do so at little cost to their sponsors and the specific research enterprise in which they are engaged.[[11]](#footnote-11)

Specifically, Merritt suggests that investigators should employ a two-step sequence to identify the ancillary care obligations they have for any particular trial. First, they should consider the candidate ancillary care needs that subjects may have, taking into account both the seriousness of the need and whether it can be addressed by individual agents – as opposed to institutions.[[12]](#footnote-12) Amongst those needs, investigators should, second, identify those to which they bear a duty to rescue by considering which needs (1) they are in a unique position to address given their expertise; (2) are otherwise likely to remain unaddressed; and (3) they can address without incurring inordinate costs.[[13]](#footnote-13)

Hawkins applies a similar analysis to the problem of standard of care, that is, the question of the level of care that investigators must provide to research subjects. She claims that investigators who conduct a placebo-controlled trial (PCT) flout their duty to rescue in cases where conducting an active-controlled trial (ACT) does not (1) impose significant personal costs; or (2) conflict with a weightier moral aim.[[14]](#footnote-14) By conducting a PCT rather than an ACT in such cases, investigators fail to meet the medical needs of their subjects when they can easily do so.

Hawkins does not think that investigators may *never* conduct PCTs, since there are conditions under which investigators’ duty to rescue is defeated. Such conditions obtain, Hawkins claims, when (1) the aim of the research is morally weighty; (2) a PCT is the only way to obtain the information in question; and (3) the community from which subjects are drawn is reasonably likely to benefit from the research.[[15]](#footnote-15) The AZT trials of the mid 1990s, Hawkins thinks, likely satisfied these criteria since the use of a placebo was necessary to establish whether a potentially life-saving intervention was effective.[[16]](#footnote-16)

2 Does the Duty to Rescue Imply Standard of Care Obligations?

We argue here that investigators do not always best fulfill their duty to rescue by either providing research subjects in the control arm with an active treatment, or by providing subjects with ancillary care. Instead, what the duty to rescue implies for any particular trial depends on variable empirical circumstances. More broadly, the problem with Hawkins and Merritt’s argumentative strategy lies in the difficulty of deriving *special* obligations–obligations to *research subjects*–from a *general* obligation that is owed to all–the duty to rescue.

Hawkins and Merritt’s accounts are distinct in important ways. Although both are aware of this potential problem with their accounts, Merritt in particular qualifies her conclusions to accommodate it, at least to some extent. In recognition of these important differences, we discuss each account separately, focusing on Hawkins’ account in this section.

Recall from above that Hawkins argues that her position on the impermissibility of certain types of PCTs ought to be enforced.[[17]](#footnote-17) Investigators should be required – as a matter of policy – to provide an active treatment to subjects in the control arm, provided that certain conditions are satisfied. Because Hawkins understands the duty to rescue to justify this requirement, she is committed to the claim that investigators ought to be required to satisfy their duty to rescue in a particular way–i.e. by providing particular types of care. But, regulations requiring investigators to satisfy their duty to rescue in a *particular* way are sometimes not consistent with investigators *fully* satisfying it–i.e. satisfying it in the best or most appropriate way. Such regulations might even *preclude* them from fully satisfying it.

How does one fully satisfy one’s duty to rescue? We claim that doing so involves (1) significantly benefitting the most people with extreme needs that one can, without (2) setting back some weighty moral aim, and (3) imposing more than minimal sacrifice on oneself. In the face of people with extreme needs, the most important moral consideration is to meet as many of these needs as possible. If one faces the choice of saving two lives or three, other things being equal, one should save three.[[18]](#footnote-18)

It is likely that in some circumstances Hawkins’ policy recommendations preclude investigators from fully satisfying their duty to rescue. If providing subjects in the control arm with an active treatment is to be consistent with investigators fully satisfying their duty to rescue, it must be the case that for investigators working in low-income countries, fully satisfying this duty always involves meeting the need addressed by the active treatment of subjects in the control arm. That is, it must not be the case that investigators could sometimes better satisfy their duty to rescue by using the resources necessary to provide such an active intervention by meeting some other need of subjects in the control arm, or the needs of people investigators encounter more broadly.

This is a tall order. It seems unlikely that in all cases investigators meet the most severe needs of subjects in the control arm by providing them with an active treatment. Participants may have other needs–whether medical or non-medical–that are more urgent. It also seems unlikely that investigators significantly benefit the most people with the most extreme needs by providing subjects in the control arm with an active intervention, as opposed to meeting the needs of those they encounter more broadly, whether trial participants or not.

Consider the following case, which illustrates these two points:

*Rotavirus*: In 2005, 2.3 million children under 5 died in India, with approximately 334,000 of these deaths attributable to diarrhoeal diseases.[[19]](#footnote-19) Of these 334,000 deaths, it is estimated that approximately 113,000–34%--were due to rotavirus infection.[[20]](#footnote-20) From March 2011–November 2012, investigators conducted a PCT at three urban and rural sites in India evaluating the efficacy of the 116e rotavirus vaccine–Rotavac–in infants.[[21]](#footnote-21) The study received funding from the Government of India, the Bill & Melinda Gates Foundation to PATH, the Research Council of Norway, and the National Institutes of Health, among others.[[22]](#footnote-22) At the time of the trial, two oral rotavirus vaccines–RotaTeq and Rotarix–had been shown to be effective in comparable low-income settings–e.g. Bangladesh–and were licensed for use in India.[[23]](#footnote-23) The market price for both vaccines was around $50 USD per dose in middle-income countries, with RotaTeq requiring 3 doses, and Rotarix requiring 2 doses.[[24]](#footnote-24) The World Health Organization recommends the inclusion of rotavirus vaccinations of infants into all national immunization programs,[[25]](#footnote-25) but two independent studies show that the introduction of a vaccine at $7 USD per dose (two-dose schedule) in India–the non-market price negotiated by Brazil–though cost-effective by international standards, is likely unaffordable for low-income countries like India.[[26]](#footnote-26) The manufacturer of Rotavac has promised to provide it at $1 per dose.[[27]](#footnote-27)

It is arguable that on Hawkins’ analysis, the investigators in *rotavirus* ought to have conducted the trial as an ACT rather than a PCT, providing subjects in the control arm with either RotaTeq or Rotarix. Both existing vaccines have been licensed in India and there are data regarding their effectiveness in comparable low-income countries, so a PCT was not necessary to determine the efficacy of the experimental vaccine Rotavac in the Indian population. Additionally, providing either RotaTeq or Rotarix to subjects in the control arm would have involved relatively little cost. If the investigators provided Rotarix to the 2267 subjects in the control arm at market rates, this would only have added $226,700 to the cost of the trial, a relatively small amount given (1) its above-mentioned wealthy sponsors; and (2) that the total cost of the project of bringing Rotavac to market has been estimated at slightly less than 50 million USD.[[28]](#footnote-28) By comparison, consider Hawkins’ treatment of the *Surfaxin* trial. In this trial, investigators proposed to conduct a PCT in Bolivia evaluating a novel, potentially life-saving surfactant therapy for premature infants, even though effective surfactant therapies are widely used in high-income countries.[[29]](#footnote-29) Hawkins argues that it would have been wrong for Discovery Labs to conduct this trial, even though the costs to Discovery Labs of conducting an ACT instead–i.e. providing the proposed 325 infants in the control arm with a standard of care surfactant therapy–would have cost at least $357,500 USD.[[30]](#footnote-30) This is more than the cost of conducting *rotavirus* as an ACT, and the burden is greater on Discovery Labs, given that it does not have the resources of *rotavirus’* funders. Presumably, Hawkins would support an ACT in *rotavirus*.

Yet, it’s highly plausible that investigators would have best satisfied their duty to rescue, not by conducting an ACT, but by providing local family caregivers and healthcare providers with the resources they require to provide local children with alternative highly effective and affordable treatments. Consider first that rotavirus vaccines are not that effective in low-income countries. RCTs evaluating the effectiveness of RotaTeq in low-income countries found that it was only 64% effective against severe rotavirus gastroenteritis in Vietnam, and 43% effective in Bangladesh.[[31]](#footnote-31) Rotavac itself was shown to be only 56.4% effective during the first year of life.[[32]](#footnote-32)

Consider second that there are a number of affordable and effective treatments for severe gastroenteritis, whether it is caused by rotavirus infection or something else. For example, a recent systematic review finds that proper use of oral rehydration solution (ORS) may reduce diarrhoeal mortality by up to 93%.[[33]](#footnote-33) Another systematic review estimates that the use of zinc is likely to reduce diarrhea mortality by 23%.[[34]](#footnote-34) Thus, in 2004, the WHO and UNICEF issued a joint statement recommending diarrhoeal disease be treated with ORS and zinc supplementation.[[35]](#footnote-35) In a recent study, Zulfiqar A. Bhutta et al. conclude that ORS and zinc treatments for diarrhoeal disease are likely to save more than twice as many lives as a rotavirus vaccine at equivalent rates of coverage in low-income countries.[[36]](#footnote-36) Additionally, these treatments are highly affordable in India. The cost of two 20g ORS sachets ranges from 0.20 to 0.35 USD and the cost of 10 tablets of 20mg Zinc Sulfate ranges from $0.45 to 0.65 USD.[[37]](#footnote-37) Treatment with ORS/zinc with a consultation with a provider ranges from 1.40 to 2.60 USD.[[38]](#footnote-38)

Consider third that many children in India do not receive ORS/zinc treatment. For example, a recent survey of management practices for childhood diarrhoea in ten districts in India found that only 38% of children suffering from diarrhoea were given ORS, and only 1% were prescribed zinc.[[39]](#footnote-39) In the states in which *rotavirus* was conducted, Delhi, Maharashtra, and Tamil Nadu, approximately 34.4%, 37.8%, and 29.0% of children suffering from diarrhoea receive ORS.[[40]](#footnote-40)

Given (1) the relatively low efficacy of existing rotavirus vaccines, and (2) the failure of many family caregivers and healthcare providers to provide highly effective and affordable treatments–ORS/zinc–in appropriate dosages, it is arguable that investigators in *rotavirus* would have best fulfilled their duty to rescue by ensuring that all subjects had access to appropriately administered ORS/zinc treatments. Investigators might do this by provisioning the clinics in which they conduct their research with ORS sachets and zinc tablets, and training family caregivers and healthcare providers to provide these treatments appropriately. This course of action is likely to better satisfy investigators’ duty to rescue for two reasons. First, these treatments are more effective than a vaccine for reducing diarrhoeal related mortality, and address cases of diarrhoea that are not only caused by rotavirus infection–only one-third of cases. Second, this course of action is likely to benefit non-participant children within the community who are likely to receive treatment from those family caregivers and healthcare providers who receive the above-mentioned training. Investigators are also likely to encounter many of these children since they are working in local clinics. In short, compared to conducting an ACT, providing family caregivers and healthcare providers with the affordable treatments mentioned above, and training them to administer them appropriately seems to offer (1) more effective treatment, (2) for more cases of diarrheoa, to (3) more people.

*Rotavirus* poses a problem for Hawkins’ analysis as it is highly plausible that investigators do not best fulfill their duty to rescue by (1) meeting the need addressed by the active treatment (diarrheoa due to rotavirus infection), of (2) subjects in the control arm. Hawkins might object here that we have not shown *definitively* that investigators would not have best satisfied their duty to rescue by conducting an ACT. For example, we have not shown that the specific clinics and communities in which *rotavirus* was conducted were ones in which ORS/zinc treatments for diarrheoa were deficient enough to make the course of action we propose superior to an ACT.

But this is just our point: the course of action that is most likely to satisfy investigators’ duty to rescue depends on the empirical context in which they will be conducting their research. Since, as our discussion of *rotavirus* shows, empirical factors may easily be such that investigators best satisfy their duty to rescue by (1) meeting needs broader or other than those addressed by the active treatment, of (2) trial participants and non-participants that investigators are likely to encounter, policy governing research should not *require* investigators to satisfy their duty to rescue in a particular way–e.g. conducting an ACT rather than a PCT. Such a requirement is likely to preclude investigators from *fully* satisfying their duty to rescue in certain circumstances.

Hawkins recognizes this potential problem with her position. In particular, she acknowledges that the duty to rescue, as a general duty, does not provide grounds for discriminating between participants and non-participants.[[41]](#footnote-41) To limit its scope to *all* and *only* participants she makes two arguments. First, she argues that its scope can be restricted to participants because it is a *limited* obligation, that is, an obligation that only requires investigators to incur limited costs, and so to only help *some* people.[[42]](#footnote-42) She argues second that the scope extends to *all* participants because of two additional moral considerations that apply to participants, but not to non-participants: *distress avoidance* and *gratitude*. On the one hand, in PCTs, members of the control group may experience mental distress that sets them apart from members of the experimental group and non-participants, namely from knowing that they had a chance at receiving a treatment for their condition but did not receive it.[[43]](#footnote-43) Investigators can eliminate this distress by conducting an ACT and so therefore the scope of their duty to rescue should be extended to cover *all* participants. On the other hand, because members of the control group contribute to medical knowledge, they are owed a debt of gratitude. Gratitude, along with the duty to rescue, Hawkins argues, gives investigators reason to provide all subjects in the control arm with an active treatment.[[44]](#footnote-44)

With respect to Hawkins’ first argument, it doesn’t follow from the fact that the obligation is a limited one that it is permissible to limit its scope to participants in a particular trial, or even that such participants fall within its scope in the first place. First, for certain types of intervention, it may be that investigators can provide it to participants *and* non-participants without incurring inordinate costs. In these cases, it would be wrong to limit the scope of the obligation to participants. Second, it’s not clear how Hawkins’ argument gives investigators a reason to include participants within the scope of the duty rather than some other arbitrarily defined group, for example, people who live in a nearby neighborhood. What is lacking is some reason to favor one group over another. Finally, there *are* positive reasons for investigators to include some individuals or groups within the scope of the duty rather than others. Since investigators fully satisfy their duty to rescue by addressing the most severe needs of the most people, they have reason to address the needs of those who are worst off, who may not always be subjects in the control arm. In cases where investigators can better satisfy their duty to rescue by not conducting an ACT rather than a PCT, they should not be required to do so.

Hawkins might be right that investigators have reasons of distress avoidance and gratitude to provide subjects in the control arm with an active treatment.[[45]](#footnote-45) However, these considerations are independent of the duty to rescue. They do not help establish the point that investigators’ duty to rescue supports a general policy of conducting ACTs rather than PCTs.

3 Does the Duty to Rescue Imply Ancillary Care Obligations?

Hawkins’ position faces the problem we identify above since she claims that (1) investigators should be required–as a matter of policy–to fulfill standard of care obligations; and (2) this duty is justified by the duty to rescue. Merritt argues that the duty to rescue justifies at least some of investigators’ ancillary care obligations, but she does not claim that investigators should be required–as a matter of policy–to fulfill these obligations, only that her two-step sequence should be considered by research ethics committees–including institutional review boards–and regulators.[[46]](#footnote-46) As such, Merritt’s position is not subject to the problem we identify with Hawkins’ view. It does not preclude investigators from fully satisfying their duty to rescue since it does not *require* them to satisfy it in one way rather than another.

Still, we think that Merritt’s account, like Hawkins’, does not fully recognize the difficulty of deriving specific obligations–i.e. obligations to provide specific forms of care to specific groups of people–from a general obligation like the duty to rescue. To illustrate this, we focus on Merritt’s two-step sequence which aims to identify the ancillary care obligations investigators possess that are implied by their duty to rescue.[[47]](#footnote-47) Recall that the first step of Merritt’s two-step sequence requires investigators to identify the candidate ancillary care needs that subjects may have, taking into account both the seriousness of the need and whether it can be addressed by individual agents–as opposed to institutions.[[48]](#footnote-48) The second step requires investigators to identify those needs to which they bear a duty to rescue by considering which needs (1) they are in a unique position to address given their expertise; (2) are otherwise likely to remain unaddressed; and (3) they can address without incurring inordinate costs.[[49]](#footnote-49) Although, as we note below, there is much of value in Merritt’s two-step sequence and that she herself acknowledges some of the problems we identify, we argue that it is too narrow in the factors it considers to adequately determine the implications of investigators’ duty to rescue. Here, we presuppose that such a decision procedure should help investigators determine the course of action that best satisfies their duty to rescue, where doing so involves (1) significantly benefitting the most people with extreme needs that one can, without (2) setting back some weighty moral aim, and (3) imposing more than minimal sacrifice on oneself.

Consider first that Merritt is not entirely clear about whether her two-step sequence is (1) a decision procedure investigators may use to determine the implications of their duty to rescue; or (2) a decision procedure investigators may use to identify the ancillary care obligations they possess that are grounded by the duty to rescue. Considered as (1), Merritt’s two-step sequence is not successful since it only considers the *ancillary care needs of subjects*. This is a problem since in certain circumstances investigators can better satisfy their duty to rescue by using the resources necessary to meet an ancillary medical need of participants by either meeting some non-ancillary medical need of participants, or meeting the medical or non-medical needs of non-participants. First, there may be cases where investigators best satisfy their duty to rescue by conducting an ACT rather than a PCT – i.e. satisfying a non-ancillary medical need of participants. Consider again the *Surfaxin* case. Arguably, investigators would have best satisfied their duty to rescue by providing subjects in the control arm with an effective and potentially life-saving treatment rather than placebo.

Second, there are likely to be cases where investigators best satisfy their duty to rescue by providing care to non-participants that they encounter, rather than ancillary care to participants. This is so since investigators often exclude subjects because of co-morbidities. Investigators encounter these subjects in the enrollment and screening process–and so are potential beneficiaries of the narrow scope duty to rescue–and they are often excluded because they have medical conditions making them worse off than those eligible to participate. For example, in *rotavirus*, children were excluded from participation if they suffered from chronic gastroenteritis.[[50]](#footnote-50) Suppose that a number of children were considered for enrollment but excluded for this reason. Given that (1) these excluded children are at greater risk of suffering from diarrhoeal disease than participants; and (2) participants generally tend to receive superior care to non-participants, particularly in low-income countries; investigators might best satisfy their duty to rescue by ensuring these children have access to appropriately administered ORS/zinc.

Consider also a hypothetical case presented by Leah Belsky and Henry S. Richardson:

HIV treatment in tuberculosis treatment trial: The trial calls for screening out patients who are HIV positive and dropping participants who seroconvert during the trial. The local standard of care for HIV and AIDS includes only palliative care. Do the researchers have a responsibility to help provide antiretroviral drugs to people they find to be HIV positive?[[51]](#footnote-51)

Provided that (1) the provision of these drugs does not interfere with the successful completion of the trial, and (2) subjects in the trial do not have medical needs more severe than this, it is possible that investigators best fulfill their duty to rescue by providing non-participants with access to antiretroviral drugs.

Merritt acknowledges this second problem with her two-step sequence, namely, that investigators may not always best fulfill their duty to rescue by providing care to *participants*.[[52]](#footnote-52) She writes:

The duty of rescue in itself, being a general duty, does not discriminate between the moral claims of research participants and those of nonparticipants amongst the prospective beneficiaries of needed interventions. So far as it is the duty of rescue that obligates researchers to provide or facilitate AC (by definition care that participants need), it may obligate them also to provide or facilitate the same interventions for similarly needy nonparticipants.[[53]](#footnote-53)

On the basis of this consideration, she concludes that investigators should only discriminate between participants and non-participants to the extent that doing so is necessary from a cost perspective. Because research participants are physically closer to investigators in virtue of being participants, it may be that investigators can help them–but not non-participants–without incurring inordinate costs.[[54]](#footnote-54) Importantly, Merritt also recognizes that such considerations may cut the other way: “considerations of cost- effectiveness might direct researchers from the outset simply to meet the relevant needs for members of the population at large, for example, by staffing a clinic that is open to one and all on demand.”[[55]](#footnote-55)

Although Merritt recognizes that the duty to rescue may require investigators to offer forms of care to non-participants, we don’t think that Merritt fully details the implications of this line of criticism for her position. Merritt frames this problem as one of precision in the two-step sequence’s assignment of ancillary care obligations to investigators.[[56]](#footnote-56) But, as we have shown above, the principal implication of our line of argument is that investigators should not presuppose that the duty to rescue is best fulfilled by providing ancillary care to subjects. In certain circumstances–e.g. the *Surfaxin* trial–investigators best satisfy this duty by providing an active treatment to subjects in the control arm, or by focusing on providing care to non-participants, for example, those who have been excluded from participation due to health problems. The real implication of our line of argument is not that Merritt’s two-step sequence is imprecise in its identification of investigators’ ancillary care obligations, but rather that its scope needs to be widened significantly. To determine what investigators should do in a particular context to fulfill their duty to rescue, investigators should not start by identifying ancillary care needs of participants as Merritt suggests,[[57]](#footnote-57) but instead by identifying the most extreme needs of those persons they are likely to encounter, whether participants or non-participants. As it is therefore, Merritt’s two-step sequence does not offer a decision procedure by which investigators can determine the implications of their duty to rescue.

Merritt might argue instead that her two-step sequence offers investigators a decision procedure by which they can determine the duty to rescue-supported ancillary care obligations they owe participants, leaving open the possibility that investigators’ duty to rescue might also imply either standard of care obligations or obligations to non-participants. The problem with this suggestion however is that it is not possible to determine whether investigators’ duty to rescue implies particular ancillary care obligations without also considering the other ways they might use the resources at their disposal, for example, to meet standard of care needs or the needs of non-participants they are likely to encounter. That is, to determine which courses of action are likely to best fulfill their duty to rescue, investigators must employ a decision procedure that asks: (1) what are types of extreme needs we are likely to encounter? and (2) which extreme needs can we meet without setting back some weighty moral aim and imposing more than minimal sacrifice on ourselves? Merritt’s two-step sequence, we would suggest, is not such a procedure, and cannot be combined with other, similar sequences to constitute such a procedure.

Whether considered as (1) a decision procedure investigators may use to determine the implications of their duty to rescue; or (2) a decision procedure investigators may use to identify the ancillary care obligations they possess that are grounded by the duty to rescue; Merritt’s two-step sequence is too narrow in the factors it considers. But, as we note above, Merritt’s idea of the two-step sequence offers a promising framework investigators may use to determine the implications of their duty to rescue in particular contexts. To be successful, the scope of this sequence need only be widened to recognize the different types of extreme needs investigators might encounter in the course of conducting research. We endorse a revised version of Merritt’s sequence in section 5 below.

4 A Professional Duty to Rescue?

We have argued thus far that Hawkins and Merritt’s argumentative strategy is unsuccessful since the duty to rescue, as a general duty, does not imply specific obligations to research participants in all cases. In response, Hawkins and Merritt might argue that investigators have a duty to rescue research subjects in particular because of their professional role. Certain professions, including police, firefighters, and doctors have an augmented, more demanding duty to rescue individuals who fall under the scope of their professional care.[[58]](#footnote-58) For instance, lifeguards, in virtue of their professional role, are responsible for enacting highly risky rescue operations to save swimmers drowning on their beach, though they would not have a more demanding duty than the average individual to run into a burning building to save a person. Doctors have a more demanding duty to rescue arising out of their professional role as well, in particular to their patients and to people in acute medical crises. The professional role of the individual gives rise to the more demanding duty to rescue in a particular domain than they would have qua individual agent. Might clinical researchers have a professional duty to rescue research subjects in particular?

Neither Hawkins nor Merritt are arguing for a special researcher duty to rescue; they explicitly employ the general duty to rescue that researchers have qua individual moral agents to derive what seems to be a special obligation to research subjects. Yet an appeal to special role morality of clinical researchers may be implicit in their thinking. Were this possibility to be explicitly developed it would face several challenges.

First, the role morality of the clinical researcher is both new and contested.[[59]](#footnote-59) It is challenging and controversial to employ role morality in arguments for researcher obligations. The role of clinical researcher lacks the long history and tradition of the ethics of the physician to draw upon in understanding the role morality. Nor is the researcher-subject relationship a familiar one to most people; we do not encounter researchers in our daily lives, if at all.[[60]](#footnote-60) Thus, it doesn’t yield a “common person” understanding of the role to guide our theorizing. The researcher role could develop in time to support certain rescue-like obligations that fall out of the special researcher-subject relationship.[[61]](#footnote-61) But we cannot shoehorn ethics into the professional role; role moralities evolve via a process guided by history, tradition, and the dialogue between ethicists and practitioners.[[62]](#footnote-62)

Second, the explicit aim of the clinical researcher—generating clinically relevant knowledge—is often at odds with the goals of individual rescue. Thus, it is not at all obvious that the role of clinical researcher supports augmented duties to rescue. The researcher’s aim is not the good of a particular person. Though researchers often have medical training, to confuse their role with that of the physician is to fall prey to the Therapeutic Misconception.[[63]](#footnote-63)

Development of researcher role morality may hold the key to arguing for researcher obligations to provide standard of care and ancillary care. Importantly, Hawkins and Merritt’s approaches ignore this possibility; they focus on grounding these obligations in general obligations of beneficence. The very nature of this approach gives rise to our concerns: such general obligations do not easily discriminate between research subjects and non-subjects as worthy recipients of rescue.

Our argument thus far, if successful, shows that it is difficult to derive special obligations, that is, obligations investigators owe to their research subjects, from the general obligation that is the duty to rescue. In what follows, we raise an even more fundamental problem for Hawkins and Merritt’s argumentative strategy.

5 Institutions and the Duty to Rescue

Hawkins and Merritt recognize that the duty to rescue is a general obligation, one that binds all persons simply qua persons, and is owed to all persons simply qua persons. In specifying the implications of this duty however, Merritt and Hawkins understand investigators not simply as persons with their own lives and resources, but instead as *professionals* having their *sponsor’s resources* at their disposal.[[64]](#footnote-64) For example, speaking of ancillary care obligations more broadly – including those grounded in investigators’ duty to rescue – Merritt describes her argumentative strategy as follows:

Sponsors’ obligations to support AC obligations…derive primarily from whatever reasons independently ground researchers’ obligations. Whenever researchers have AC obligations for those reasons, the financial burden of meeting them is reasonably assigned to sponsors.[[65]](#footnote-65)

Hawkins describes her argumentative strategy in similar terms:

It seems to me that a good argument can be made that researchers, just like the rest of us, have Good Samaritan obligations . . . . When researchers go to [low-income countries], they knowingly enter an environment where people they could easily save are dying all around them…These cases also satisfy the condition on excessive personal sacrifice: the nonmoral interests at stake here are those of the sponsors who have an interest in running cheap, effective trials. Still, the cost of additional medical supplies is (usually) not too expensive for these sponsors and so would not be a huge sacrifice.[[66]](#footnote-66)

For both Merritt and Hawkins therefore, investigators incur a duty to rescue qua individuals. But, when it comes to determining the actions investigators must perform to fulfill this duty, investigators are understood as professionals having the resources of their sponsors at their disposal. After all, the actions that Hawkins and Merritt claim are required by researchers’ individual duty to rescue–i.e. the provision of an active intervention or ancillary care–while requiring little sacrifice for many sponsors of research, would likely bankrupt many researchers. This is a problem for Hawkins and Merritt’s strategy since it is difficult to understand how investigators’ *individual* duty to rescue could require them to use their *sponsors’ resources* to provide either ancillary care or an active intervention to research participants.

Consider Hawkins and Merritt’s strategy in more formal terms:

1. Investigators have a duty to assist others in extreme need in cases where doing so (a) does not conflict with some weighty moral aim; (b) requires little personal sacrifice; and (c) is likely to significantly benefit the recipients.
2. Investigators can significantly benefit some of their research participants in extreme need by providing ancillary care/an active intervention, (a) without giving up some weighty moral aim; and (b) incurring only little personal sacrifice.
3. Investigators have a duty to provide some of their research participants with ancillary care/an active intervention.

The above-mentioned problem emerges with premise 2. To determine whether it is true, we need to determine which actions would involve little personal sacrifice. To determine this however, we need to know the amount of resources investigators have at their disposal, such that the provision of certain forms of care to participants would constitute a small personal sacrifice.

There are two ways to do this. The first is to use a *moralized metric*, understanding the amount of resources investigators have at their disposal to be the amount of resources that they have a right to use to pursue their private purposes. In a reasonably just society, this amount would be equivalent to investigators’ private assets. On a *non-moralized metric*, by contrast, the amount of resources at investigators’ disposal is simply the amount of resources they can get their hands on, regardless of whether doing so involves violating the property rights of others.

On either of these metrics however, premise 2 is false in the vast majority of circumstances. If Hawkins and Merritt employ a moralized metric, (2) is false since the provision of either ancillary care or an active intervention will involve a great sacrifice on the part of most investigators–i.e. those who are not extremely wealthy. Hawkins and Merritt might argue that a moralized metric should include a sponsor’s resources as well as investigators’ private assets. But, it is deeply misleading to suggest that investigators have the same normative relation to their sponsor’s resources that they have to their own private assets–i.e. that they have a right to use them to pursue their private purposes. Sponsors themselves are moral agents with rights to determine the purposes to which their resources are put. It is simply a mistake to claim that once an individual holds the office of investigator, the resources of her sponsor are suddenly normatively equivalent to the resources she possesses as a private individual. Consider the following case:

*Executive*: Robin is a senior executive at a successful investment bank. Each day as she walks to work, she encounters people who are homeless, lack medical care for a variety of chronic and mental illnesses, and rarely have enough to eat. She discovers that there is a charity in the neighborhood working to address the problems of these people. The strategies it employs have proven to be effective, but it lacks the funding necessary to make a truly significant impact given the number of people in need. Robin recognizes she owes a duty to rescue to these people and decides to donate some money. Should she include the bank’s resources as resources she has a right to employ to pursue her private projects?

No. Occupying the office of executive does not imply that Robin has a right to use the bank’s resources to pursue her personal projects. Instead, the bank, understood as a collective agent, possesses such a right. On a moralized metric, to determine what Robin owes to the people she encounters on her way to work, we look to her private assets.

The same is true of researchers and their sponsors. The mere fact that an individual inhabits the role of researcher does not imply that the sponsor’s resources become *her own*. The individual duty to rescue binds researchers qua individuals, and so to determine what it demands, we look to the private resources and capabilities of the researcher, not the resources and capabilities of the sponsor.[[67]](#footnote-67)

Hawkins and Merritt might object here that at least in certain cases, the investigator-sponsor relation is different from Robin’s relation to her employer. In many cases after all, investigators function less like employees of their sponsors as opposed to entrepreneurial independent contractors responsible both for the study budget, and for conducting the study in an ethically responsible manner.[[68]](#footnote-68) Why not think that to conduct their studies ethically, investigators must budget some of their sponsor’s resources to meet the extreme needs of those they are likely to encounter?

It may be that the investigator-sponsor relation is different from Robin’s relation to her employer in many circumstances, but we don’t think that this matters. Hawkins and Merritt still need to explain why investigators should consider their *sponsor’s resources* as their own *private resources* for the purposes of determining what their individual duty to rescue requires. The mere fact that an investigator is an independent contractor does not imply that the sponsor’s resources become her own. Consider a slightly different case:

*Grant:* Steve is an education policy researcher. He wants to study the effectiveness of an intervention targeted at low-achieving grade 4 students and is applying for a state government grant to carry out the research. He knows that the schools he will study are located in high-poverty areas and that on his frequent site visits, he will likely encounter people who are homeless, lack medical care for a variety of chronic and mental illnesses, and rarely have enough to eat. Steve recognizes that upon meeting these individuals, he will have a duty to rescue them. In determining how much aid he should provide them, should he consider the sponsor’s resources as his own private resources? Should he include in his research budget funds to meet the extreme needs of those he is likely to meet?

No, the fact that Steve is best understood as an independent contractor in this case rather than an employee does not mean that the sponsor’s resources become his own private resources for the purposes of determining the requirements of his individual duty to rescue. The funding state in question has the right to determine how its resources will be used, not its employees, and not the persons with whom it contracts.

Investigators should of course use their sponsor’s resources to ensure that their trials are conducted ethically. After all, to fulfill many of their duties to participants–e.g. to secure participants’ informed consent–investigators will need assistance from their sponsors. But, it makes little sense to say that investigators require assistance from their sponsors to fulfill their duty to rescue. As an individual duty, what the duty to rescue requires of investigators is already indexed to the resources they possess qua private individuals.

Is (2) true if Hawkins and Merritt adopt a non-moralized metric, according to which people are to consider any resources they can get their hands on–including the resources of others–as their own? No. Apart from the counter-intuitiveness of this metric–it implies that one is entitled to employ any resources one can get one’s hands on to pursue one’s private purposes–this metric does not render (2) true in most cases. First, if investigators use their sponsor’s resources to provide either ancillary care or an active intervention, they risk great personal sacrifice in cases where sponsors do not authorize such usage. The penalties for such actions can include both termination of employment and legal action.

Second, such unauthorized use of their sponsor’s resources may also conflict with the successful conduct of research–a morally weighty activity. Publicly sponsored research, particularly in low-resource settings, is often conducted with the goal of developing treatments that are responsive to the extreme needs of local people. Privately sponsored research also has an important role to play in bringing new pharmaceutical products to market. If investigators use their sponsor’s resources without authorization, they might unjustly prioritize easy rescues over other ways of saving and improving lives.[[69]](#footnote-69) That’s not to say sponsors have no obligation to help with rescues because their other work is morally weighty.[[70]](#footnote-70) But researchers using sponsor resources without their consultation circumvents any priority-setting process or consideration. Merritt and Hawkins’s argument should not rely upon the assumption that rescue is always the better way to use a set of resources. Similarly, respect for the system of private property itself is a morally weighty goal, both insofar as it allows people – as individuals or collectives – to make use of external objects to set and pursue goals; and insofar as it is the basis of much economic growth and development. [[71]](#footnote-71) For the sake of wide appeal and plausibility, Merritt and Hawkins’s view should not commit them to a radical conception of property rights—one where ownership of resources can be undermined if the resources are not being put to the best use.

Hawkins and Merritt might argue that premise (2) is true in cases where sponsors *grant* investigators a wide range of discretion regarding resource use. In such cases, wouldn’t investigators’ individual duty to rescue imply a duty to provide either ancillary care or an active intervention to some of their participants? [[72]](#footnote-72)

On a moralized account, it depends on the nature of the discretion that is granted. If, in the unlikely event, a sponsor grants the investigator *total* discretion regarding the use of the sponsor’s resources such that the resources are normatively equivalent to the investigator’s own private resources, then (2) might be true. But, as seems more likely, if investigators are simply granted wide discretion regarding the use of sponsor resources to design the study, then (2) is false. In such a case, the resources do not become the investigator’s *own*; rather the investigator is simply given discretion regarding the use of the sponsor’s resources to achieve the goal of producing of clinically relevant knowledge. On a non-moralized account, (2) might be true in cases where investigators are granted a level of resources sufficient to make the provision of either ancillary care or an active intervention a small sacrifice.

The larger problem with this line of argument is that it yields only a toothless view of the researcher duty to rescue. On the assumption that individually bearing the costs of providing either ancillary care or an active intervention would be too burdensome to a researcher, this view amounts to saying that there is a duty to provide such care only if the sponsor grants investigators wide discretion regarding the use of its resources. The force of the duty to provide such care is dependent upon the sponsor’s good will. What this view fails to account for is the fact that the sponsors are *obligated* to provide rescue. The sponsor is implicated in this obligation—not the ultimate authority on how the purse strings *should* be held. Moreover, Merritt and Hawkins are unlikely to be satisfied with this position. Since they take their conclusions to be policy relevant–i.e. binding on investigators and their sponsors–they require an account that explains why the obligation to provide certain types of care to participants is not conditional on the good will of sponsors.

Importantly, nothing we say here implies that researchers working in low-income countries are not permitted to use the resources of their institution to help the people in extreme need that they encounter. Our point is only that the *justification* for such actions cannot rely solely on the individual duty to rescue. Instead, one must argue that (1) the institution in question possesses a duty to rescue; and (2) researchers are permitted to use the institution’s resources to discharge its duty. In the following section of this paper, we rely on this strategy to provide an alternative the duty to rescue and its implications for the conduct of clinical research in low-income settings.

6 The Institutional Duty to Rescue and International Research

Hawkins and Merritt’s accounts are motivated by the intuition that researchers and their sponsors have a duty to meet the extreme needs of people they encounter in the course of conducting research in low-income countries. We share this intuition. But Hawkins and Merritt leave an explanatory gap between the fundamental individual duty to rescue of researchers, and the responsibility of sponsors to devote their resources to rescue. As long as Hawkins and Merritt see as fundamental the individual duty to rescue, they will struggle to get the second desiderata of their view: that sponsors are also implicated in rescue. We suggest a way forward, starting not from a *personal* duty to rescue, but instead from an *institutional* one. This starting point will explain why both sponsors and researchers come to have duties to rescue, resolving the second problem with Hawkins and Merritt’s view. As we’ve said previously, we do not think the first problem—the derivation of a special researcher obligation to subjects from a general obligation—can or should be resolved. Our approach also has the advantage of explaining how and why researchers and sponsors’ duty to rescue is constrained by the value of important medical research.

We propose that high-income states have an institutional duty to rescue and that this duty obligates them to require government-funded research agencies and their investigators to use the public resources at their disposal to meet the extreme needs of people they encounter in low-resource settings, whenever doing so (1) is likely to significantly benefit them; (2) is consistent with the successful realization of the agency’s research projects; and (3) imposes minimal opportunity costs. We do not discuss the important question of whether other collective agents that currently fund clinical research, including private-for-profit corporations and non-governmental organizations, also possess institutional duties to rescue. While there is widespread agreement that high-income states possess such a duty, whether other collective agents do so is controversial, and we do not have the space in this paper to decide this question.[[73]](#footnote-73) Our view will have wide application nonetheless, given that many research enterprises are at least partially government funded.[[74]](#footnote-74)

Scholars disagree about the nature and justification of an institutional duty to rescue. Is it owed to individuals or populations?[[75]](#footnote-75) Is it a general obligation or a special obligation (i.e. is it owed to particular individuals or particular populations?) Is it derivative of the personal duty to rescue, and merely an instrument by which individuals can better discharge their personal duties?[[76]](#footnote-76) Or, is the institutional duty to rescue a distinctively political duty that applies to institutions qua institutions?[[77]](#footnote-77)

For the purposes of this paper, we need not take a position on all of these questions, and we shall not do so. It is not our aim to formulate an account of the institutional duty to rescue, but rather to understand its implications for researchers and their sponsors working in low-income countries. We focus on the claim that high-income states possess a general obligation to assist persons in extreme need in cases where doing so (1) does not conflict with some weighty moral aim; and (2) does not prevent them from realizing their legitimate aims and responsibilities, for example, providing their own citizens with access to health care and education.

To accomplish this task, it is sufficient to note that this duty is widely supported by political theorists, if only as a minimal requirement of justice;[[78]](#footnote-78) and, that high-income states have committed themselves to some variant of this duty, pledging to devote 0.7% of GNP to developmental assistance, and to help realize the United Nations Millennium Development Goals by 2015, which include the eradication of extreme poverty and hunger, improvements to maternal health, reductions in child mortality, and combatting HIV/AIDS, Malaria, and other diseases. High-income states currently discharge their institutional duty to rescue–to the extent that they do so–through the creation and funding of national and international aid agencies–e.g. USAID, the UN World Food Program, and the UN Children’s Fund; and through the provision of aid to governments of low-income countries. Given its wide support amongst both political theorists and policy-makers of high-income countries, this understanding of the institutional duty to rescue offers a strong foundation for the claims we argue for below.

Despite the work of these agencies and the development projects of low-income governments, many people still have extreme needs and are in need of rescue. This is partly due to the unwillingness of many high-income countries to fully discharge their institutional duty to rescue by allocating a sufficient level of resources to their aid budgets. But, it is also partly due to the challenges aid agencies and low-income governments face in implementing sustainable and effective development programs, even when they are adequately funded, and the corruption of many low-income governments.[[79]](#footnote-79) A consequence of this is that investigators working in low-income countries often encounter people with unmet extreme needs.

High-income states should of course meet the aid commitments they’ve made. But, given that (1) the politicians of many high-income states are unlikely in the near future to support a substantial increase in development aid budgets; and (2), even if increases could be expected; aid agencies and low-income governments still face the challenge of developing effective and sustainable development programs. Investigators working in low-income countries are likely to encounter people with extreme needs for the foreseeable future. How might high-income states better fulfill their institutional duty to rescue in the face of these circumstances?

We suggest that high-income states should require their research agencies and investigators to use the public resources at their disposal to meet the extreme needs of people investigators encounter in low-income countries when, and to the extent that, (1) agencies and their investigators have the capability to do so; and (2) doing so does not interfere with the successful short and long term realization of the agency’s research projects. In cases where it is possible for agencies to fulfill their mandate and meet the extreme needs of the people their investigators are likely to encounter and that will not otherwise be met, they should be explicitly required to do so. In this way, high-income states can better fulfill their institutional duty to rescue, using their resources to meet as many needs as possible, while at the same time not prioritizing immediate rescue over research enterprises informing potentially highly valuable interventions.

Importantly, in contrast with Hawkins and Merritt, we do not think that this requirement necessarily implies that investigators should improve the standard of care for subjects in the control arm or provide ancillary care to all participants, though it might require either under certain circumstances. Since high-income states have a duty to rescue all persons in extreme need, they should direct their agents to use the public resources at their disposal to do the most good that they can, whether this means meeting the extreme needs of participants or non-participants, medical or non-medical. In the course of planning a research project in a low-income country, investigators and research agencies should ask: with respect to the particular context in which we will conduct our research, which extreme needs might we meet given the resources and capabilities we will have on the ground without (1) interfering with the research project; and (2) imposing significant costs on the agency and its personnel? Indeed, a broadened version of Merritt’s two-step sequence–one that is not focused only on the *ancillary care* needs of *subjects*–offers a promising procedure for identifying these needs. Agencies and investigators could first consider the candidate extreme needs of the people investigators are likely to encounter, taking into account both the seriousness of the needs and whether they can be addressed by individual agents as opposed to institutions. They could second identify those needs which (1) they will be in a unique position to address given the expertise on the ground; (2) are otherwise likely to remain unaddressed; and (3) they can address without incurring inordinate costs.[[80]](#footnote-80)

One might argue here that the institutional duty to rescue implies that states should not fund clinical research in low-income countries and instead use the resources saved to meet the extreme needs of people in these countries. In response, consider first that clinical research, particularly the type of clinical research high-income countries fund in low-income countries which tends to target the medical needs within these countries, is a morally weighty activity and a legitimate purpose of high-income states. The institutional duty to rescue–as we define it–does not therefore imply that high-income states must stop funding clinical research in low-income countries. Indeed, given the wealth of high-income societies, high-income states can fund clinical research *and* fulfill their duty to rescue at the same time.

Because funding clinical research in low-income countries is a morally weighty activity of high-income states moreover, it follows that state-funded research agencies and their investigators have no obligation grounded in the duty to rescue to use the resources authorized and necessary for research to meet the extreme needs of those they encounter. The institutional duty to rescue does not require, whether of states or their agents, that they prioritize rescue over clinical research, a morally weighty activity.

Additionally, investigators and their sponsoring agencies have a *pro tanto* duty to use the public resources authorized for research to carry out their research projects, rather than using these resources to meet extreme needs. First, investigators and their sponsoring agencies, like all agents, have a *pro tanto* obligation to respect the decisions of legitimate governments regarding the use of public resources. Legitimate states have a right to decide how their resources will be used, and people have a *pro tanto* obligation to respect and obey these decisions.[[81]](#footnote-81)

Second, investigators and agency executives have a *pro tanto* duty of fair play to fulfill their respective institutional obligations, as they are defined by their role within the broader institutional structure. By a duty of fair play, we mean a duty to perform one’s role as defined by the rules of an institution in cases when (1) the institution is reasonably just; and (2) one has voluntarily accepted the benefits of the role in question.[[82]](#footnote-82) The positions of investigators and agency executives arguably satisfy these conditions since they confer professional and monetary benefits on their occupants and most high-income states are reasonably just.

Importantly, the *pro tanto* obligation of investigators and their sponsoring agencies to carry out their research projects is a genuine *moral* obligation, not merely a *legal* obligation. Our point is not that investigators and their sponsoring agencies are bound by law to use the resources at their disposal for authorized purposes, but rather that the fact that they are bound by the law of a legitimate political institution matters morally. Since citizens have a *pro tanto* moral duty to obey the laws of the legitimate political institutions to which they are subject, investigators and their sponsors have a *pro tanto* moral obligation to use the resources at their disposal for their legally authorized purposes.

We acknowledge that this duty is *pro tanto,* however; it can be outweighed by other considerations, specifically, when three conditions are satisfied: (1) the community in which an agency is working is hit by an unexpected catastrophe; (2) the resources at the disposal of investigators could be used to meet the extreme needs of community members; and (3) there is no time or procedure by which the agency’s resources can be reauthorized for this purpose. In such a case, any reasonable government would authorize a change in the use of the resources in question, and so it is permissible for investigators to proceed on the assumption that such a reauthorization has occurred.

We do not think however that investigators are morally permitted to use their sponsor’s resources for rescue rather than research anytime they can meet the extreme needs of people they encounter – i.e. when (2) is satisfied but not (1) or (3). In our view, this suggestion does not adequately recognize the moral value of compliance with the law of legitimate political institutions. Such compliance matters morally both instrumentally and non-instrumentally. It matters instrumentally since failure to comply with the law is likely to negatively impact the ability of the state to accomplish its goals. If investigators working in low-income countries regularly use the resources authorized for research for rescue, the state in question is unlikely to continue allocating resources for clinical research, not only putting an end to potentially valuable research, but also stripping investigators of the resources they would like to use for rescue. Compliance with the law also matters non-instrumentally since the laws of legitimate political institutions represent the collective decision citizens have made about the rules to govern their interaction and the use of their collective resources.[[83]](#footnote-83) As the result–in democratic states–of a decision procedure that gives each citizen’s view equal weight, legislation deserves the *respect* of its citizens.[[84]](#footnote-84)

What about cases where high-income states are not fulfilling their institutional duty to rescue? Do agency executives and investigators have an obligation to devote the resources authorized for research to meeting extreme needs? No. Just as high-income states need not sacrifice morally weighty activities to meet extreme needs, neither must their agents. In cases where states are not fulfilling their institutional duty to rescue, the resources necessary to do so should not be drawn from morally weighty activities like biomedical research.

What should investigators and their sponsoring agencies do in cases where the government has not authorized the use of its resources to meet the extreme needs of citizens of low-income countries? May they use public resources to meet these needs, provided that such use (1) does not interfere with their successful realization of their research projects, and (2) imposes minimal costs on the agency?

This is a challenging question. On the one hand, since states have a duty to rescue, they do not seem to be in a position to complain if their agents use their resources to help fulfill this duty.[[85]](#footnote-85) On the other hand investigators and research agencies should respect their government’s legitimately enacted decisions regarding the use of public resources. If their government authorizes resources to be used for clinical research, they should not be used for alternative purposes.

We think that it is permissible for agencies and investigators to use public resources to meet the extreme needs of citizens of low-income countries–subject to the satisfaction of (1) and (2)–in cases where states have not expressly forbidden their agencies from doing so. In cases where states have neither expressly forbidden agencies from using public resources in this way nor expressly authorized them to do so, there is a sense in which the agencies in question and their investigators lack direction and so must make an executive decision. Since the use of public resources to meet the extreme needs of citizens of low-income countries is consistent with states’ duty to rescue, we think it is reasonable to conclude that it is permissible for research agencies and their investigators to do so.

But, although it is *permissible* for agencies and investigators to use public resources to meet extreme needs in such circumstances, we do not think that they always have an *obligation* to do so. Qua institutional agents, the responsibility of investigators and other state agents is limited to carrying out their mandate. It is the responsibility of states and their officials to determine the purposes with which agencies’ resources should be used, including how the institutional duty to rescue is to be fulfilled. Additionally, investigators and agency executives may risk significant personal costs–e.g. loss of employment–if they employ public resources in an unauthorized way–i.e. violate institutional policies. Qua persons, although the state’s agents do have a personal duty to rescue, as we note above, this does not require them to use public resources to meet the extreme needs of those they encounter.

In “Collectivizing Rescue Obligations in Bioethics,” Jeremy R. Garrett also notes the value of considering the duty to rescue as an institutional duty rather than as a personal duty in this context, and considers the implications of this duty for genomic researchers making incidental findings.[[86]](#footnote-86) We understand Garrett’s analysis to be largely complementary to our own, but our account is distinctive in an important way. Apart from considering the implications of the institutional duty to rescue for research agencies and investigators working in low-income countries, our analysis also recognizes the normative significance of the *institutional context* within which investigators work. That is, we recognize that most rescues in the context of clinical research will involve the use of public resources and that this raises difficult questions since: (1) the use of public resources is subject to law; and (2) investigators and research agency executives have a *pro tanto* duty to comply with the law of legitimate political institutions. Our analysis is distinctive in that it recognizes these questions as genuine moral questions, and aims to solve them, providing an account of what investigators and agency executives should do in cases where the resources at their disposal have not been publicly authorized for rescue.

How do our conclusions differ from those of Hawkins and Merritt? First, the focus on the institutional duty to rescue rather than the personal gets the order of explanation right: states have duties to rescue in low-income settings that are inherited by sponsors and researchers acting as agents of the state. This puts the primary responsibility for rescue in researcher encounters on *states,* not researchers. Researchers derive responsibilities to carry out duties to rescue when authorized to do so by their sponsor. In cases where sponsors have neither authorized nor forbidden such use, researchers are permitted to act in accordance with their state’s duty to rescue, though not required to do so at personal cost. Next, our approach constrains the duty to rescue to situations where rescue would not impede the research aims of a study. Our approach recognizes the value of research and provides an explanation for how and why research should be balanced with rescue goals—i.e. states have both duties to rescue in low and middle income settings as well as a permission to fund and conduct clinical research. The duties of researchers to rescue are both derived from and limited by the obligations of the state to its public and to countries in need of aid. Unlike Hawkins and Merritt’s account, our account explains the source of the duties of researchers to meet the extreme needs of those they encounter, and it does so plausibly, by tying them to the state.

In contrast to Hawkins and Merritt, we do not think that either the institutional or personal duty to rescue has direct implications for investigators’ standard of care or ancillary care obligations. Instead, what agencies and investigators should do to fulfill these duties is context dependent. In some circumstances agencies and their investigators may best fulfill these duties by providing all participants with ancillary care or improving the standard of care for subjects in the control arm; in others, they may best do so by providing care to participants and non-participants alike. With respect to policy, our analysis does not therefore imply that investigators possess any additional concrete obligations that ought to be enforced by regulatory bodies. Instead, state sponsors of research should require their agencies to meet the extreme needs of people in low-income countries when doing so (1) does not interfere with the realization of their mandate; and (2) imposes few opportunity costs. Although Hawkins and Merritt are correct that investigators and other state agents possess a personal duty to rescue, we do not think such a duty provides a legitimate basis for regulations to provide any particular kind of care.

Conclusion

We have argued that recent use of the duty to rescue by bioethicists to justify specific, policy relevant requirements of clinical investigators—such as standard of care and ancillary care obligations— is misguided. Bioethicists are hard-pressed to explain why investigators have obligations to research participants in particular when the duty to rescue is a general obligation. Further, focus on the personal duty to rescue ignores the institutional context in which investigators work. We argue, instead, that what the duty to rescue requires in any particular situation is highly context dependent. It cannot provide support for a system of specific rules or regulations to govern different types of research trials in all contexts. We also advocate understanding investigators’ duty to rescue as an institutional duty— one that is held by a collective agent and inherited by a representative agent. We do not deny that investigators possess a *personal* duty to rescue, but, given the limited resources of investigators qua persons, we think it is more important to focus on the duty to rescue possessed by high-income states. This duty entails that states should require their research agencies and investigators to use public resources to meet the needs of people in low-income countries when doing so does not interfere with their research aims and poses minimal cost on the agency. Absent concrete direction, investigators are permitted to use public resources to meet extreme needs in low-income countries when doing so does not conflict with their research aims and the cost to the agency is minimal. Our analysis of investigators’ duty to rescue continues the recent tradition of advocacy for a robust duty to rescue on the part of agents of high-income countries, but we properly situate this duty in the institutional context, and we reject policy proposals regarding the discharge of this duty that are too restrictive.

1. More demanding versions of the duty to rescue require persons to help others in extreme need in cases where doing so does not require them to sacrifice anything of comparable moral importance. See Peter Singer, “Famine, Affluence, and Morality,” *Philosophy and Public Affairs* 1 (1972): 229-243; and Peter Unger, *Living High & Letting Die: Our Illusion of Innocence* (New York: Oxford University Press, 1996). [↑](#footnote-ref-1)
2. See Jennifer S. Hawkins, “Exploitation and Placebo Controls,” in *Exploitation and Developing Countries: The Ethics of Clinical Research* (Princeton: Princeton University Press, 2008): 246-285. [↑](#footnote-ref-2)
3. Mariah W. Merritt, “Health Researchers’ Ancillary Care Obligations in Low-Resource Settings: How Can We Tell What Is Morally Required?” *Kennedy Institute of Ethics Journal* 21 (2011): 311-347. [↑](#footnote-ref-3)
4. Ibid, 313; Hawkins, “Exploitation and Placebo Controls,” 275-277. [↑](#footnote-ref-4)
5. Hawkins, “Exploitation and Placebo Controls,” 266; Merritt, “Health Researchers’ Ancillary Care Obligations,” 317. [↑](#footnote-ref-5)
6. Tina Rulli and Joseph Millum, “Rescuing the Duty to Rescue,” *Journal of Medical Ethics.* Published Online First 30/04/2014 doi: 10.1136/medethics-2013-101643, 3. [↑](#footnote-ref-6)
7. See Singer, “Famine, Affluence, and Morality.” [↑](#footnote-ref-7)
8. Ibid, and Unger, *Living High & Letting Die*. [↑](#footnote-ref-8)
9. By ancillary care, Merritt follows Henry S. Richardson and Leah Belsky in meaning “health care that research participants need but that is not necessary to ensure the safety or scientific validity of the research, to redress injuries caused by research participation, or to fulfill morally optional promises,” “Health Researchers’ Ancillary Care Obligations,” 312. For Richardson and Belsky’s original definition see Henry S. Richardson and Leah Belsky, “The Ancillary-Care Responsibilities of Medical Researchers,” *Hastings Center Report* 34 (2004): 26. Importantly, Richardson and Belsky distinguish the duty to rescue from ancillary care obligations that are incumbent on investigators. Ibid. [↑](#footnote-ref-9)
10. Merritt recognizes that investigators may also have further ancillary care obligations that are grounded in the investigator-subject relation. Merritt, “Health Researchers’ Ancillary Care Obligations,” 336. [↑](#footnote-ref-10)
11. Ibid, 336-337. [↑](#footnote-ref-11)
12. Ibid. [↑](#footnote-ref-12)
13. Ibid. [↑](#footnote-ref-13)
14. Hawkins, “Exploitation and Placebo Controls,” 267. [↑](#footnote-ref-14)
15. Ibid, 273. [↑](#footnote-ref-15)
16. Ibid, 273-275. [↑](#footnote-ref-16)
17. Ibid, 275-277. Note that Hawkins provides additional reasons – apart from her moral analysis – to justify such enforcement. See Ibid. [↑](#footnote-ref-17)
18. This formulation of the duty to rescue is not precise enough to function as a principle of resource allocation. Priority setting questions are the subject of a large literature and resolving them is beyond the scope of this paper. Additionally, we need not specify the duty to rescue further for our purposes here. [↑](#footnote-ref-18)
19. Shaun K. Morris et al., “Rotavirus Mortality in India: Estimates Based on a Nationally Representative Survey of Diarrhoeal Deaths,” *Bulletin of the World Health Organization* 90 (2012), 720. [↑](#footnote-ref-19)
20. Ibid, 722. [↑](#footnote-ref-20)
21. Nita Bhandari et al., “Efficacy of a Monovalent Human-bovine (116E) Rotavirus Vaccine in Indian Infants: A Randomised, Double-Blind, Placebo-Controlled Trial,” *The Lancet* 383(2014): 2137. [↑](#footnote-ref-21)
22. Ibid, 2136. [↑](#footnote-ref-22)
23. Ibid, 2136, 2140-2141; and Sudhir Babji and Gagandeep Kang, “Rotavirus Vaccination in Developing Countries,” *Current Opinion in Virology* 2 (2012), 444. [↑](#footnote-ref-23)
24. Jacob Puliyel and Joseph Mathew, “Should India Launch a National Immunisation Programme Against Rotavirus? No,” *BMJ* 345 (2012), e7832. [↑](#footnote-ref-24)
25. World Health Organization, “Rotavirus Vaccines: WHO Position Paper – January 2013,” *Weekly Epidemiological Record* 88 (2013), 62-63. [↑](#footnote-ref-25)
26. See Johnie Rose et al., “Public Health Impact and Cost Effectiveness of Mass Vaccination with Live Attenuated Human Rotavirus Vaccine (RIX4414) in India: Model Based Analysis,” *BMJ* 339 (2009): b3653; and Douglas H. Esposito et al., “Projected Impact and Cost-Effectiveness of a Rotavirus Vaccination Program in India, 2008,” *Clinical Infectious Diseases* 52 (2011): 171-177. [↑](#footnote-ref-26)
27. Bharat Biotech, “Bharat Biotech Announces the Price of Rotavac its Potential Vaccine against Rotavirus Diarrhoea,” News Release, June 6, 2011; available at: http://www.bharatbiotech.com/wp-content/plugins/prs/pdf/BBIL-GAVI-ROTAVAC-Press%20Release-06June2011-F.pdf. [↑](#footnote-ref-27)
28. Roger Glass, “The Neonatal Rotavirus Vaccine Project (Strain 116E) Rotavac: A Brief Review for the 25th Anniversary of the Indo-US Vaccine Action Program (VAP),” available at: http://www.fic.nih.gov/News/Publications/Pages/roger-glass-neonatal-rotavirus-vaccine-project-article.aspx. [↑](#footnote-ref-28)
29. Discovery Labs proposed the trial for the purposes of testing Surfaxin for eventual use in the U.S. and European markets—not as an emergency intervention or eventual standard of care for infants in Bolivia. “Case Studies: The Havrix Trial and the Surfaxin Trial,” in *Exploitation and Developing Countries: The Ethics of Clinical Research*, ed. Jennifer S. Hawkins and Ezekiel J. Emanuel (Princeton, NJ: Princeton University Press, 2008), 58-61. [↑](#footnote-ref-29)
30. Ibid; and Hawkins, “Exploitation and Placebo Controls,” 266-277. [↑](#footnote-ref-30)
31. See K Zaman, “Efficacy of Pentavalent Rotavirus Vaccine Against Severe Rotavirus Gastroenteritis in Infants in Developing Countries in Asia: A Randomised, Double-Blind, Placebo-Controlled Trial,” *The Lancet* 376 (2010): 615-623. [↑](#footnote-ref-31)
32. Bhandari et al., “Efficacy of a Monovalent Human-bovine (116E) Rotavirus Vaccine in Indian Infants,” 2139. [↑](#footnote-ref-32)
33. Melinda K. Munos, Christa L. Fischer Walker, and Robert E. Black, “The Effect of Oral Rehydration Solution and Recommended Home Fluids on Diarrhoea Mortality,” *International Journal of Epidemiology* 39 (2010): 75-87. [↑](#footnote-ref-33)
34. Christa L. Fischer Walker and Robert E. Black, “Zinc for the Treatment of Diarrhoea: Effect on Diarrhoea Morbidity, Morality and Incidence of Future Episodes,” *International Journal of Epidemiology* 39 (2010): i63-i69. [↑](#footnote-ref-34)
35. WHO/UNICEF, *Clinical Management of Acute Diarrhoea* (New York: WHO/UNICEF, 2004). [↑](#footnote-ref-35)
36. Zulfiqar A. Bhutta et al., “Interventions to Address Deaths from Childhood Pneumonia and Diarrhoea Equitably: What Works and at What Cost?” *The Lancet* 381 (2013), 1424-1425. [↑](#footnote-ref-36)
37. Clinton Health Access Initiative, *The Private Sector Market for Diarrhea Treatment in India*, 44. [↑](#footnote-ref-37)
38. Ibid. [↑](#footnote-ref-38)
39. UNICEF, *Management Practices for Childhood Diarrhoea in India: Survey of 10 Districts*, 4-5. [↑](#footnote-ref-39)
40. National Family Health Survey India, 2005-2006. [↑](#footnote-ref-40)
41. Hawkins, “Exploitation and Placebo Controls,” 269-270. [↑](#footnote-ref-41)
42. Ibid, 270. [↑](#footnote-ref-42)
43. Ibid, 270-271. [↑](#footnote-ref-43)
44. Ibid, 272. [↑](#footnote-ref-44)
45. Though, one could imagine Hawkins’ claims about distress avoidance applying to non-participants not selected to participate in research. Subjects excluded because they did not meet the eligibility requirements are also likely to experience distress and not receive the superior care that trial participants are likely to receive, even if they are in the control arm. Thanks to JM for this point. [↑](#footnote-ref-45)
46. [↑](#footnote-ref-46)
47. Merritt, “Health Researchers’ Ancillary Care Obligations,” 336. [↑](#footnote-ref-47)
48. Ibid, 336-337. [↑](#footnote-ref-48)
49. Ibid. [↑](#footnote-ref-49)
50. Bhandari et al., “Efficacy of a Monovalent Human-bovine (116E) Rotavirus Vaccine in Indian Infants,” 2137. [↑](#footnote-ref-50)
51. Leah Belsky and Henry S. Richardson, “Medical Researchers’ Ancillary Clinical Care Responsibilities,” *BMJ* 328 (2004), 1496. [↑](#footnote-ref-51)
52. Merritt, “Researchers’ Ancillary Care Obligations,” 341. [↑](#footnote-ref-52)
53. Ibid. [↑](#footnote-ref-53)
54. Ibid, 341-342. [↑](#footnote-ref-54)
55. Ibid, 342. [↑](#footnote-ref-55)
56. Ibid, 341. [↑](#footnote-ref-56)
57. Ibid, 336. [↑](#footnote-ref-57)
58. See Rulli and Millum, “Rescuing the Duty to Rescue,” 3-4. [↑](#footnote-ref-58)
59. See Benjamin Sachs, “The Exceptional Ethics of the Investigatory-Subject Relationship,” *Journal of Medicine and Philosophy* 35 (2010): 64-80; Steven Joffe and Franklin G. Miller, “Bench to Bedside: Mapping the Moral Terrain of Clinical Research,” *Hastings Center Report* 38 (2008): 30-42. [↑](#footnote-ref-59)
60. Sachs, “The Exceptional Ethics of the Investigatory-Subject Relationship,” 75. [↑](#footnote-ref-60)
61. For an example, see Belsky and Richardson’s work on ancillary care obligations. Though see our commentary in what follows. [↑](#footnote-ref-61)
62. Hawkins and Merritt cannot be viewed in engaging in this process, as they are arguing for specification of a general duty to rescue rather than the special role morality of researchers. [↑](#footnote-ref-62)
63. Joffe and Miller, “Bench to Bedside: Mapping the Moral Terrain of Clinical Research,” 40; Sachs, “The Exceptional Ethics of the Investigatory-Subject Relationship,” 77. [↑](#footnote-ref-63)
64. As Rulli and Millum make clear, Hawkins and Merritt are not the only bioethicists to define the duty to rescue as a general obligation that applies to persons but to then apply it to professionals operating within an institutional context. Rulli and Millum, “Rescuing the Duty to Rescue,” 3. [↑](#footnote-ref-64)
65. Merritt, “Researchers’ Ancillary Care Obligations,” 323. [↑](#footnote-ref-65)
66. Hawkins, “Exploitation and Placebo Controls,” 267. [↑](#footnote-ref-66)
67. One might object that our position presupposes that we can cleanly distinguish between the resources and capabilities of researchers qua private individuals and those of researchers qua institutional actors. A researcher working in a low-income setting might find it difficult to determine which resources and capabilities are her own and which are her sponsors for the purposes of determining what her individual duty to rescue requires. We grant researchers may face difficult cases in this regard. But, they will also face easy cases, and the situations Hawkins and Merritt have in mind fall in this latter category. After all, the question of the treatment to be offered to participants in the control arm, or that of the types of ancillary care to be offered to all participants, are cases where it is clear that researchers are deciding how to spend their sponsor’s resources. Thanks to an anonymous reviewer for raising this concern. [↑](#footnote-ref-67)
68. Thanks to an anonymous reviewer for raising this consideration. [↑](#footnote-ref-68)
69. The Rule of Rescue states the common psychological tendency of people to prioritize as more morally urgent salient rescue cases over improvements in well-being to unidentifiable others. See Jonsen A. Bentham in a box: technology assessment and health care allocation. Law Med Health Care 1986;14(3–4):172–74; McKie J, Richardson J. The rule of rescue. Soc Sci Med 2003;56(12):2407–19. [↑](#footnote-ref-69)
70. None of our arguments rely upon the consequentialist assumption that either party is morally required to optimize. [↑](#footnote-ref-70)
71. For a development of this line of argument with respect to the duty to rescue, see David Schmidtz, “Islands In a Sea of Obligation: An Essay on the Duty to Rescue,” *Law and Philosoph****y*** 19 (2000) 683-70. [↑](#footnote-ref-71)
72. We thank an anonymous reviewer for this suggested interpretation of the view. [↑](#footnote-ref-72)
73. For a discussion of the implications of different accounts of the duties of private-for-profit corporations for the ethics of for-profit clinical research, see Douglas MacKay, “Standard of Care, Institutional Obligations, and Distributive Justice,” *Bioethics* 29 (2015): 262-273. [↑](#footnote-ref-73)
74. We are not the first to note the value of considering the duty to rescue from an institutional perspective in bioethics. See Rulli and Millum, “Rescuing the Duty to Rescue;” Jeremy R. Garrett, “Collectivizing Rescue Obligations in Bioethics,” *The American Journal of Bioethics* 15 (2015): 3-11; and Nancy S. Jecker, “Rethinking Rescue Medicine,” *The American Journal of Bioethics* 15 (2015): 12-18. As we explain below however, our discussion of the implications of the institutional duty to rescue in the context of clinical research is distinctive in a number of important ways. [↑](#footnote-ref-74)
75. See Rulli and Millum, “Rescuing the Duty to Rescue,” 3. [↑](#footnote-ref-75)
76. See Liam B. Murphy, “Institutions and the Demands of Justice,” *Philosophy and Public Affairs* 27 (1998): 251-291. [↑](#footnote-ref-76)
77. See Arthur Ripstein, “Three Duties to Rescue: Moral, Civil, and Criminal,” *Law and Philosophy* 19 (2000): 751-779. [↑](#footnote-ref-77)
78. See Peter Singer, *One World: The Ethics of Globalization* (New Haven: Yale University Press, 2002); Simon Caney, *Justice Beyond Borders: A Global Political Theory* (New York: Oxford University Press, 2005); Martha C. Nussbaum, *Frontiers of Justice: Disability, Nationality, Species Membership* (Cambridge: Harvard University Press, 2006); David Miller, *National Responsibility and Global Justice* (New York: Oxford University Press, 2007); Thomas Pogge, *World Poverty and Human Rights: Cosmopolitan Responsibilities and Reforms*, 2nd ed. (Cambridge, UK: Polity Press, 2008); Gillian Brock, *Global Justice: A Cosmopolitan Account* (New York: Oxford University Press, 2009); and Michael Blake, *Justice and Foreign Policy* (New York: Oxford University Press, 2013). [↑](#footnote-ref-78)
79. For an overview of the debates regarding the effectiveness of different aid approaches and the broader challenges of developing effective sustainable aid programs, see Abhijit V. Banerjee and Esther Duflo, *Poor Economics: A Radical Rethinking of the Way to Fight Global Poverty* (New York: Public Affairs, 2011). [↑](#footnote-ref-79)
80. Merritt, “Health Researchers’ Ancillary Care Obligations,” 336-337. [↑](#footnote-ref-80)
81. For defense of this claim, see Jeremy Waldron, *Law and Disagreement* (New York: Oxford University Press, 1999), 101-118; Christopher Heath Wellman, “Towards a Liberal Theory of Political Obligation,” *Ethics* 111 (2001): 735-759; Thomas Christiano, *The Constitution of Equality: Democratic Authority and its Limits* (New York: Oxford University Press, 2008), 243-258; and George Klosko, *Political Obligations* (New York: Oxford University Press, 2005). [↑](#footnote-ref-81)
82. Rawls, *A Theory of Justice*, 96. By a reasonably just state here, we mean a state that secures for all citizens equal basic liberties, including democratic political rights, and redistributes income to ensure that all citizens can satisfy their basic needs. [↑](#footnote-ref-82)
83. Waldron, *Law and Disagreement*, 109-118. [↑](#footnote-ref-83)
84. Ibid. [↑](#footnote-ref-84)
85. For example, see Frances Kamm’s example of a rescuer borrowing the boat of another—who is far away on vacation—in order to rescue a person. She argues that because the boat owner would have a duty to rescue were he on the scene, the actual rescuer can help him discharge this duty by using his boat. Frances Kamm, “Does Distance Matter Morally to the Duty to Rescue?” *Law and Philosophy* 19 (2000), 673. [↑](#footnote-ref-85)
86. Garrett, “Collectivizing Rescue Obligations in Bioethics.” [↑](#footnote-ref-86)