*This is the finally accepted version of this paper. It is not the version of record. For that, please see* [*https://doi.org/10.1007/s10677-022-10360-2*](https://doi.org/10.1007/s10677-022-10360-2)

**Title: Institutional Review Boards and Public Justification**

ABSTRACT: Ethics committees like Institutional Review Boards and Research Ethics Committees are typically empowered to approve or reject proposed studies, typically conditional on certain conditions or revisions being met. While some have argued this power should be primarily a function of applying clear, codified requirements, most institutions and legal regimes allow discretion for IRBs to ethically evaluate studies, such as to ensure a favourable risk-benefit ratio, fair subject selection, adequate informed consent, and so forth. As a result, ethics committees typically make moral demands on researchers: require them to act in a way the committee considers ethically right or appropriate. This paper argues that moral demands are legitimate only if publicly justifiable; and as a result, committee decisions are subject to a public justification requirement. Ethics committees can permissibly request for more information, changes to the research protocol or that the research is delayed or even stopped only if these demands are publicly justifiable. This latter claim is in turn justified on the basis that moral demands to φ are permissible only if we are in a position to know that the addressee ought to φ and that we are in a position to know a proposition only if it is publicly justifiable.

This argument suggests that ethics committees must consciously and explicitly appeal to public reasons in their decision-making. In cases where public reasons cannot be offered, committees would not be permitted to reject a given study or make approval conditional on an amendment.

Keywords: Institutional Review Boards, Moral Demands, Public Justification, Knowledge and Disagreement

**1. Introduction**

Institutional Review Boards (IRBs), or Research Ethics Committees as they are known in some jurisdictions, often seek a social license for research by providing a credible signal to the larger public that researchers are behaving ethically (Dixon-Woods and Ashcroft 2008, London 2022). In attempting to generate this signal, there is a worry that IRBs may overreach by policing too much. Indeed, the restrictions they place on researchers, the arbitrariness and bureaucratisation are sources of frustration for many researchers (Hyman 2007, Kotsis and Chung 2014, Moore and Donnelly 2018, Briggs 2022). This overreach is plausibly caused by ethics boards erring on the side of restricting or delaying research where there is reasonable disagreement about its permissibility[[1]](#footnote-1). IRBs are much more wary of permitting research that is too risky than of stopping or delaying potentially valuable research (Hyman 2007). One reason for this, in part, is that reasons favouring permitting research has been cashed out primarily in consequentialist terms where restricting research has opportunity costs and permitting research is good because of the contribution to everyone’s welfare. (London 2022, Briggs 2022). Meanwhile, reasons to restrict researchers appeal to both deontological terms (Stark 2007) concerning special obligations towards research subjects, as well as consequentialist considerations of protecting participant’s wellbeing (Kotsis and Chung 2014) as well as promote public trust in research[[2]](#footnote-2) (London 2022, Dixon-Woods and Ashcroft 2008). Because deontological considerations are not often provided against restricting researchers, there is an asymmetry of reasoning that arguably tends to favour more restrictions. This paper attempts to remedy this lacuna by providing some non-consequentialist conditions on when research can permissibly be restricted. Specifically, we adopt a public reason framework: IRB decisions which restrict researchers[[3]](#footnote-3) (hereafter IRB decisions) are permissible only if the decisions are publicly justifiable.

One factor that may enable this overreach and hence contribute to arbitrary decisions is the fact that IRBs have, depending on the jurisdiction, varying levels of discretion to go beyond the content of written laws. For instance, laws like the US Common Rule (1981), National Health Medical Research Council Act (1992) in Australia (NHMRCA) and the Human Biomedical Research Act (HBRA) in Singapore (2015) regulate the conditions under which informed consent is taken. Even when applying these pre-existing laws, IRBs have discretion as to how these laws are to be interpreted and what is actually required of researchers (Stark 2007). Depending on the jurisdiction[[4]](#footnote-4), such laws may also give broader authorisation[[5]](#footnote-5) to regulate research and even though some laws may reference ethical documents like the Helsinki Declaration or Belmont Report, the principles are usually so broad as to allow significant levels of discretion. Moreover, social science research and biomedical research on embryos and non-humans may, in some jurisdictions[[6]](#footnote-6), fall outside the admittedly broad discretion that is conferred by these laws. Even here, institutions and journals may require IRB approval and impose professional and academic consequences even when there is no legal requirement. This discretion can serve to explain at least some of the variation in standards that exists between institutions. For simplicity, this paper will focus its analysis on those instances where the IRB exercises such discretion. However, this should not be taken to imply that the public justification requirement has no purchase when the IRB lacks discretion.

Our paper is structured as follows: Section 2 presents and defends the central argument of this paper: IRBs make moral demands[[7]](#footnote-7) and a moral demand is permissible only if it is publicly justifiable. Section 3 briefly explores some of the implications of a public justification requirement applying to IRBs. Section 4 addresses the objection that the public justification requirement has little bite because researchers can be contractually obligated to comply with IRB demands regardless of their public justifiability.

**2. The Moral Demands Argumen**t

Let us make the central argument of this paper, which we will defend in more detail in the rest of this section, more explicit. Here is what we shall call the Moral Demands Argument:

1. IRB decisions make moral demands on researchers (and members of the public)
2. A moral demand is permissible only if it is publicly justifiable
3. An IRB decision is permissible only if it is publicly justifiable (from 1 and 2)

In section 2.1 we defend the first premise, namely, the claim that IRB decisions make moral demands on researchers. In 2.2, we defend the second premise according to which a moral demand is permissible only if it is publicly justifiable. This will be done by articulating and defending an argument we call the Knowledge Argument. The claim the IRB decisions are permissible only if publicly justifiable follows trivially from these two premises.

Before proceeding to defend each premise of this argument, we should take some time to clarify exactly what claim we are making when we say that IRB decisions ought to be publicly justifiable. Our approach to clarifying this is to ascertain what political liberals are committed to in claiming that laws ought to be publicly justifiable and extend this in a natural way to IRB decisions.

To start with, an IRB decision is publicly justifiable if and only if the underlying proposition can be justified to all suitably idealised agents (Gaus 2011, Larmore 2015, Rawls 1993). For instance, if an IRB decides to reject a certain research proposal by researcher Y, said decision is publicly justifiable if and only if the underlying proposition “Y ought not to go through with the research proposal” is justifiable to all suitably idealised agents. A proposition is justifiable to someone if and only if it would be uniquely rational for her to believe it. By this, we mean that only believing, not suspending judgment or disbelieving, the proposition would be rational for her. This falls out of a plausible way of cashing out the public justification intuition (Muralidharan forthcoming). After all, if “justifiable to” did not mean at least “uniquely rational to believe,” it would be possible for a proposition P to be justifiable to all suitably idealised agents but still subject to reasonable disagreement by those agents. However, reasonable disagreement about P is incompatible with P being publicly justifiable. Hence, P is justifiable to someone if and only if it is uniquely rational for her to believe P.

To be clear, this is consistent with some reasonable disagreement about which policy is best being compatible with each of those policies being publicly justifiable. For instance, between health care policy options A and B, both A and B could be publicly justifiable as long as it was uniquely rational for each suitably idealized agent to believe that either policy was permissible. If someone, however, rationally believed that A was actually impermissible, it is hard to see how a decision to implement A could be justifiable to her. Public justifiability of a policy only requires no reasonable disagreement about its permissibility, not about whether it is best.

According to public justification theorists, something goes wrong when a state imposes a law on the basis of sectarian moral or metaphysical views. What goes wrong is not that view in question is false, but that it is subject to reasonable disagreement (Rawls 1993, Larmore 2015). Public justification theorists take reasonable disagreement between suitably idealised agents to be the kind of disagreement that undermines public justification. Two people can reasonably disagree about a proposition if they can have different but still reasonable degrees of belief about the proposition. The most plausible view about reasonable belief, is that a belief is reasonable only if it is epistemically rational (Enoch 2017, Muralidharan forthcoming)[[8]](#footnote-8).

One argument, roughly, is that if we know that a person’s belief falls short of rationality, we are at least sometimes permitted to demand that she reason better. However, political liberals are also committed to the claim that if her belief is reasonable, we are not permitted to demand that she reason better since doing so violates a duty of restraint. Political liberals believe that we have a duty of restraint to at the very least, refrain from endorsing laws, the permissibility of which, are subject to reasonable disagreement. Since others can reasonably reject the law, demanding that they reason better so that they revise their beliefs and endorse the law violates the duty of restraint. If it were possible for a belief to be reasonable for someone, yet fall short of rationality, it would be both permissible and not to demand that she reason better. Since the latter is incoherent, a belief counts as reasonable only if rational (Muralidharan forthcoming).

Given this account of reasonable belief, public justification is undermined so long as suitably idealised agents can rationally disagree about the corresponding proposition. If a proposition is not uniquely rational for all suitably idealised agents to believe, they can rationally disagree about it. Therefore, a demand is publicly justifiable only if it is uniquely rational for all suitably idealised agents.

Cashing out public justifiability also requires giving some account of the suitably idealised agent. Instead of a precise account, we will provide some theoretical considerations to motivate why we may need some notion of idealisation while leaving it open exactly how much idealisation is required by the theory. Plausibly rational disagreement by wicked persons is not the kind of thing which should undermine the legitimacy of a demand. The mere fact that sociopaths or amoralists might rationally reject a given law does not make that law illegitimate. If it did, political liberalism would entail anarchism. Yet, political liberals are typically not anarchists. Hence any plausible specification of public justifiability must idealise the constituency of justification in some way. Yet, if we were to idealise this constituency so thoroughly that they are conceived of as accepting what we take to be the correct moral theory, we vitiate the motivating intuitions behind public justification theorising. This sets a ceiling on how much we could idealise agents: Idealised agents will not always possess the correct moral views on all matters. Given these two considerations, for the purposes of this paper, we will assume that at least the following idealisation holds: Idealised agents care about doing the right thing and also care about figuring out what that is. Nothing we say here guarantees their success, only that this is what they aim at and that they will take appropriate steps to satisfy these aims. Readers are free to add in further substantive moral constraints (within reasonable limits) so as to form a plausible account of the constituency of justification.

In addition to the above moral constraints on the idealised agent, we think that the following epistemic constraint is also appropriate: evidential non-inferiority. No suitably idealised agent is evidentially inferior to another. We can define evidential inferiority as such

Evidential Inferiority: One agent Alf is evidentially inferior to another agent Betty with regards to a proposition P if and only if a) Betty possesses all the evidence that A possesses with respect to P as well as some crucial evidence that A does not possess or b) only B’s evidence with regards to P is decisive.

The motivation behind this is Mill’s Bridge case (Mill 2009, 163-164). Liberals, following Mill, have typically thought it permissible to paternalistically interfere with others’ decisions in at least some cases where those others are lacking some crucial piece of evidence. Mill raises the example where someone wishes to cross a bridge, but does not know that the bridge is not safe. However, supposing we do know that it is unsafe, then we are permitted to interfere with their decision to cross, at least until they have been adequately informed. Similarly, we can imagine cases where people reject certain laws and demands simply because they lack some crucial piece of information. For instance, the mere existence of creationists who are ignorant (whether or not blamelessly so) about the fossil record does not make a national syllabus which requires teaching the theory of evolution illegitimate. Any plausible account of public justification will want to rule out rational disagreements which arise from these sorts of evidential asymmetries as undermining the public justifiability of those laws.

Having spelled out what we mean by ‘publicly justified’, we will now turn to defending each premise of the Moral Demands Argument.

**2.1 IRBs and Moral Demands**

The first premise is that IRBs make moral demands. Plausibly, at least some of the things IRBs do involve making moral demands. In this section we will defend the more ambitious claim that most of the things IRBs, especially in how they relate to researchers, do involve making moral demands. IRBs recommend changes to a research proposal, require researchers to provide detailed information for both initial and ongoing review, delay a study or may either allow or disallow a study to proceed (Stark 2007, Klitzman 2011). Of these, allowing a study to proceed without modifications does not involve moral demands since the relevant illocutionary act is not performed, but the other four activities do involve making moral demands, or so we shall argue. Our strategy here is to first briefly provide and defend an account of a moral demand and then show that IRB decisions which aim to restrain researchers fit this account.

To explain what we mean by moral demand, we shall first spell out what we mean by a demand: Alf demands that Betty φ if and only if Alf issues a directive to φ to Betty and Alf means that φ-ing is, in some respects, non-optional. Correspondingly, we shall define a moral demand in the following way:

Moral Demand: A morally demands that B φ if and only if a) A issues a directive to φ to B, b) A means that φ-ing is morally non-optional.

One upshot of this account of moral demand is that it allows that people may issue a moral demand even if they are rationally mistaken about what morality requires in a given instance. Intuitively, it must be possible for people to issue moral demands even if they have misleading evidence about what morality requires. For instance, a paramedic might, given her best judgment, morally demand that a bystander perform CPR on an individual in distress even if she could not have known that doing so would cause further injuries to her.

Notice that for something to count as a moral demand, it must be a) a directive which is b) meant as morally non-optional. Clearly recommending changes, requiring information, delaying and disallowing studies involve issuing directives. What may be disputed is the other component of moral demands.

Consider, first, the non-optionality component. We have good reason to think that any such recommendation is not merely a suggestion. Suppose that the IRB recommended certain changes to the experimental protocol. If researchers did not wish to comply with the recommendation, they would be expected to produce a good reason for failing to do so. However, when I make a mere suggestion, you do not *need* to give me a reason as to why you do not follow my suggestion. Instead, this need to produce reasons suggests that IRB recommendations are demands. A sufficiently good reason by the researcher does not make the directive optional. Instead, the directive is withdrawn. It is characteristic of these sorts of cases that optional directives are not issued. Where the IRB understands φ-ing to be optional, it tends to remain silent.

The final part to showing that IRBs make moral demands is to show that IRBs are committed to the claim that if researchers ought to provide detailed information, amend the research proposal, delay or even stop the study, these obligations are moral obligations. Some of these demands will explicitly be moral. For example, requirements of fair subject selection (not unfairly excluding some participants, or placing excessive burdens on others) (Mackay 2016) invoke moral language. Informed consent is generally defended in terms of promotion of moral values of autonomy, harm minimization and so forth.

It might initially seem as if other IRB demands may not be moral, such as demands to provide additional information, or to implement more rigorous methodologies are scientific or epistemic demands whereas demands to format proposals in a way that is easier for IRBs to evaluate are self-interested ones. However, the mere fact that some demands are scientific does not also mean that they are not implicitly moral demands as well.

In the scientific case, the risks that subjects/patients undertake can be morally justified only if there is a sufficiently good scientific payoff. Unnecessarily shoddy methodology will result in poor science and poor science cannot justify imposing risks on the public (Emanuel, Wendler and Grady 2000, CIOMS 2016). Crucially, part of the institutional mandate of IRBs is to ensure that the research is morally justified in this respect as well[[9]](#footnote-9). Board members are, or at least ought to be, conscious of this when they make demands on researchers. Hence if there is a requirement to improve the scientific rigour of a given study, then this would be a moral requirement.

In cases like formatting the research proposal in certain ways, this too is implicitly a moral demand. Commonly, presenting one’s research proposal clearly is a matter of being professional. We could also further ground this requirement in concerns of distributive justice. Research and its ethical regulation is a joint enterprise (London 2022). One standing moral consideration in joint enterprises is that the burdens of cooperation be fairly distributed. Arguably, making IRBs do all the interpretive work unfairly distributes the burdens of the enterprise. The demand to format proposals properly is a demand on researchers to shoulder their share of the burden of this endeavour. This point can be generalised for all these seemingly self-interested demands. These should show that if there is a requirement to present one’s research proposal clearly, it would be a moral requirement.

Given that such directives that IRBs would issue are meant as morally non-optional, most IRB decisions are moral demands.

**2.2 Moral Demands and Public Justification**

According to the second premise of the Moral Demands Argument, it is wrong to make a moral demand if it cannot be publicly justified. To argue for this claim, consider the following argument (which we shall defend in greater detail) we call the Knowledge Argument:

1. It is wrong for Alf to morally demand that Betty φ if Alf is not in a position to know that Betty ought to φ.
2. If the proposition that “Betty ought to φ” is not publicly justifiable, Alf is not in a position to know that “Betty ought to φ”
3. It is wrong for Alf to morally demand that Betty φ if the proposition that “Betty ought to φ” is not publicly justifiable. (from 1 and 2)

**2.2.1 The absence of knowledge**

According to the first premise, it is morally wrong for Alf to demand that Betty φ if he is not in a position to know that Betty ought to φ. Such a demand would be wrong because it involves Alf treating Betty as subject to his will. The latter, in turn is wrong because it is authoritarian: treating someone as subject to one’s will fails to respect them as free and equal moral agents. In the rest of this sub-section, I shall show how Alf’s demand that Betty φ when he is not in a position to know that she should φ treats her as being subject to his will. The strategy here is to explore a series of cases, each of which involves Alf not being in a position to know that Betty ought to φ. Exploring each case in this series gives us reason to think that the next case also involves an authoritarian and hence impermissible attempt to impose Alf’s will on Betty.

There are three kinds of situations whereby Alf may not be in a position to know that Betty ought to φ. Firstly, it may be that Betty may permissibly refrain from φ-ing. Secondly, it may be that even if Betty ought to φ, Alf is not justified in believing this to be the case. Lastly, even if Alf is justified and it is true that Betty ought to φ, this belief may still fall short of knowledge because there is something that breaks the systematic connection that normally exists between justification and truth. In all three cases, what makes demanding that Betty φ amount to imposing Alf’s will is that there is some kind of gap between the demand and what Betty ought to do. I shall account for each situation in turn.

Where it is permissible for Betty to not-φ, we might consider two types of cases. The first, is an obviously authoritarian one whereby Alf believes that Betty acquires a duty to φ, when she previously did not, because of his demand. Imagine that Alf knows that prior to his demand, Betty has no obligation to get him a cup of coffee. However, he mistakenly believes that his making such a demand creates a duty for Betty to bring him a cup of coffee. This sort of belief is explicitly authoritarian. We can also dispose of a nearby type of case where Alf does not believe that demanding that Betty φ creates a duty. Such a case would involve a kind of Quasi-Moorean incoherence (Adler 2002, Horowitz 2014, Smithies 2019). From the first-person perspective, it seems incoherent to say to Betty “φ but you are not obligated to φ”. However from the third person perspective it would be perfectly coherent to say that Alf demands that Betty φ but she is not obligated to φ. This suggests, that as with Moorean infelicities, Alf demanding that Betty φ pragmatically implies that he believes that Betty ought to φ.

A second, more relevant, type of case involves Alf falsely believing that Betty really ought to φ. For instance, suppose Alf falsely believes that Betty ought not to have an abortion. Here we might worry that since Alf’s demand is made in good faith and he genuinely believes that Betty ought not to have an abortion independently of his demand, then the demand is not authoritarian.

Alf can be unintentionally authoritarian here because his demand that Betty not abort does not connect to what morality actually requires of her in the right way. As Gaus (2011) notes, the freedom and equality of persons means that no person’s will can be rightfully subsumed by another. To distinguish attempts to get people to act morally from pushing them around, Gaus suggests that issuing moral demands is problematic *because* “morality does not fax its demands down from above” (2011, 11). However, having moral knowledge is as good as morality faxing its requirements from above since the latter is merely one (fantastical) way of having moral knowledge. This suggests that only with moral knowledge is the connection between the authoritative moral truth and the demand robust. Without it, it would be only our wills that guide the demand. Since Alf’s belief is false, he is not merely attempting to get Betty to act morally. After all, if his attempt had succeeded and Betty refrained from having an abortion, he would have, despite his best intentions, subjected Betty’s will to his own.

The next two types of situations involve ones where Alf has a true belief about what Betty ought to do which still falls short of knowledge. Consider, first, those cases where Alf’s true belief is not justified by either his or Betty’s evidence. For instance, Betty is prescribing treatment A to a patient. Against all available evidence, the patient is allergic to treatment A and should take treatment B instead. Betty’s colleague Alf, without considering the evidence carefully, demands that Betty prescribe B instead. Here too Alf’s demand is authoritarian. Even though the thing Alf is getting Betty to do happens to be the right thing, this congruence is merely coincidental. Since the moral truth is not robustly connected to the demand, only Alf’s will is guiding the demand. As such, it is authoritarian.

We can extend the above analysis to cases where Alf’s justified, true belief about what Betty ought to do still falls short of knowledge. While we might think that justified beliefs are systematically connected to the truth, this connection breaks down in cases where they fall short of knowledge. Consider Gettier cases wherein the truth of a justified belief is a matter of luck. For instance, while driving through a country in which almost all the things that look like barns are merely cleverly crafted barn facades, Betty comes across the only real barn and it is burning. Betty ought to stop and check to see if anyone needs help. Alf demands that she stop and see if anyone needs help.

The usual systematic connection between justification and truth is absent in such cases. If Alf’s belief that Betty ought to help is Gettiered, then there is no robust connection between Alf’s demand and Betty’s obligations. It is merely a matter of luck that Alf’s demand coincides with what Betty ought to do. Here too, only Alf’s will guides the demand.

To generalise, whenever Alf is not in a position to know that Betty ought to φ, Alf’s demand that she φ lacks a systematic connection to what she ought to do. This is because knowledge is precisely that state whereby the truth of an agent’s belief is not lucky. Whenever Alf’s demand lacks such a connection, Alf’s will alone guides the demand. Therefore, Alf’s demand attempts to subject Betty to his will. On the other hand, when Alf is in a position to know that Betty ought to φ, Alf is simply communicating the force of the authoritative moral requirement that she is properly subject to and not merely attempting to subject Betty to his will.

**2.2.2 Public Justification and Knowledge**

We can now turn to the second premise of the Knowledge Argument: For any proposition, P, if P is not publicly justifiable, then Alf is not in a position to know that P. To see why, recall that P is not publicly justifiable if and only if suitably idealised agents could rationally disagree about P. To see how rational disagreement could undermine knowledge, we can consider the case where there is rational disagreement about whether a particular course of treatment is sufficiently risky that it would be wrong for physicians to prescribe it[[10]](#footnote-10). Let us call the claim that the course of treatment is too risky TREATMENT. We can consider two variants of this case: ones in which all the relevant evidence is shared and ones where at least some of the evidence is not shared. We will first show that of the different accounts of how people can rationally disagree given the same evidence, some entail that knowledge is undermined because the belief is lucky that it is justified and true, some entail that at least one of the disagreeing agents is not suitably idealised and the remaining are implausible. We then examine cases of rational disagreement where people have different evidence. Here, either one of the agents is not suitably idealised or knowledge is undermined because someone luckily did not encounter a defeater.

Consider, first, the case where evidence is shared. In cases where evidence is the same either people can rationally disagree (Ballantyne and Coffman 2011, Rosa 2012, Rosa 2016, Schoenfield 2014, Meacham 2014, Kelly 2014) or they cannot (Matheson 2011, White 2014, Anantharaman 2015). If they cannot, then the proposition is publicly justifiable since suitably idealised agents would not reasonably disagree. Consider, now, the possibility that two people with the same body of evidence can rationally disagree about a proposition. Even if both of them were rational in their doxastic attitudes, neither would count as knowing the relevant proposition. The reason for this is that in order for an agent, Alf, to know that TREATMENT is true, the truth of his justified belief must not be lucky. However, where it is possible that Alf could rationally fail to believe TREATMENT even though he has the same evidence, even if his justified belief that TREATMENT is true, he is lucky his belief is true. After all, he could have just as easily reasoned properly on the same total body of evidence but ended up with a false belief instead.

One might worry that this is too quick. After all, it might be that the agent who reasons her way to TREATMENT could not have reasoned any other way because of her epistemic standards (Schoenfield 2014). The thought is that what is rational for an agent depends on her epistemic standards as well as her evidence. The epistemic standard governs precisely how the agent reasons from the evidence she has. Rational disagreement given the same evidence is possible because people have different epistemic standards. However, this raises the question as to why the agent has one epistemic standard rather than another. On one account (Schoenfield 2014, Callahan 2019), agents choose their own epistemic standards. So long as the standard is permissible, the resultant belief is rational. On such an account, since no further rational considerations go into determining how to choose epistemic standards, then, in permissive cases, it is simply a matter of luck that the agent’s justified beliefs turn out to be true. After all, the agent could just as easily have adopted another epistemic standard instead.

Of course, there are other accounts of how people’s epistemic standards can permissibly differ which do not rely on them being arbitrarily chosen by the agent. Crucially, on one view, an agent’s epistemic standard depends on her cognitive capacities[[11]](#footnote-11). The thought here is that since agents have different cognitive capacities, different epistemic standards are appropriate for different agents (Simpson 2017). Suppose that inferring that TREATMENT requires integrating information from a range of studies with different results. For those who are able to integrate this information, they should adopt an epistemic standard which requires them to infer that the treatment is too risky. For those who are unable to integrate this information, they should adopt standards that require them to suspend judgment or do something other than integrate information from these disparate studies.

Notably this account presupposes that agents’ cognitive limitations can bear on which epistemic standard to adopt. After all, the agent whose cognitive capacities are not limited would be rational in believing what her evidence entails, but someone with limited cognitive capacities could rationally suspend judgment even with the same evidence. Plausibly, utilising one’s capacities to respond to the evidence properly and thereby arrive at a true belief is at least a necessary ingredient of knowledge. The fact that people with more cognitive limitations, through no fault of their own, could not respond to the reasons properly does not undermine knowledge. If this account of rationality is successful, it might seem as if someone can be in a position to know a proposition which is not publicly justifiable.

However, there is good reason to think that, contrary to appearances, such propositions are publicly justifiable. Arguably, suitably idealised agents are not less than maximally competent reasoners. The reason for this is that especially in weighty matters, disagreement by less than maximally competent persons is not the kind of thing which provides reason for us to exercise restraint in appealing to a given principle (Leland and van Wietmarschen 2012). According to Leland and van Wietmarschen, only disagreement by reasoners at *all* levels of competence can provide a reason to refrain from appealing to the disputed proposition. If this is right, then political liberals are already prepared to regard such propositions where rational disagreement arises only out of cognitive limitations of one of the parties as being publicly justifiable.

In addition, we can also put pressure on such accounts of rationality. What motivates Simpson’s (2017) cognitive capacity view is the thought that in cases where our cognitive capacities are inadequate, attempting to evaluate the evidence is more likely to lead you to error than ignoring that evidence. We might imagine that for someone whose cognitive capacities are not up to the task, if they were to try to integrate conflicting information from different studies, they would end up falsely believing that not-TREATMENT. Thus, where one’s cognitive capacities are lacking, not considering the studies and suspending judgment is better than trying to integrate the information and failing badly.

However, this move ignores the distinction between the reliability of a particular reasoning process like properly integrating conflicting information or *modus ponens* and the reliability with which an agent can carry out *modus ponens* or properly integrate conflicting information. Imagine a highly careless logician nevertheless successfully proves a theorem without making a mistake in this instance. Intuitively, the logician’s belief is rational. Surely what matters in evaluating the rationality of the logician’s belief is whether he actually reasoned well in this instance, not whether he normally reasons well. Yet, if Simpson’s view is correct, then facts about the logician’s poor track record about reasoning well swamps the fact that he reasoned well in this one instance. As a result, he would never be able to improve his track record. But this is implausible.

This lesson applies equally in our case where the poor reasoner is unable to reliably integrate conflicting information. The mere fact that he is unable to reliably do so does not mean that if he were to successfully integrate the information (perhaps with some prompting and assistance), he would be justified in his belief. Suppose that instead, he was completely unable to properly integrate the conflicting information[[12]](#footnote-12). Even in this case, the mere fact that an agent is unable to make a highly reliable inference does not mean that reliable cognition does not require that inference. Once we recognise the distinction between the reliability of an inferential process and the reliability with which an agent carries it out, we can see that the latter is irrelevant for epistemic justification. And hence the inability of an agent to carry out said piece of reasoning does not justify the agent in not making that inference. We have seen in the case where agents have different cognitive capacities, either their disagreement is not rational, or, even if rational, does not undermine public justification.

We can make the same claim about a similar view of rationality: People with the same evidence might rationally disagree because everyone, even the best among us are cognitively limited and cannot be considering all our evidence all the time (Podgorski 2016a, 2016b). For instance, suppose Alf and Betty’s body evidence consists of various studies some of which suggest that TREATMENT and others which suggest otherwise. Since neither have infinite cognitive resources, Alf and Betty may permissibly stop considering all their evidence at some point (Gaus 2011, Peels and Booth 2014). Suppose Alf starts with considering the cases that favour TREATMENT while Betty starts with the cases that suggest the opposite. If they each stop short of considering all their evidence, then it is possible for Alf to believe TREATMENT and Betty to believe otherwise and both to be rational. Thus, even the most cognitively gifted among us can rationally disagree given the same evidence. Alf is still in a position to know[[13]](#footnote-13) that TREATMENT is true because if he were to properly consider all his evidence, he would justifiably believe a truth in a non-lucky way. Here too would seem to be a case of rational disagreement between suitably idealised agents which does not undermine knowledge.

However, it is a mistake to think that this is an instance of rational disagreement. Here is why: accounts of rationality like the above depend on a distinction between a proposition being worth believing and it being rational or responsible (Booth and Peels 2010, Peels and Booth 2014) to believe the proposition. In Betty’s case, the two come apart. It is not worth believing not-TREATMENT given her evidence. Yet, it is, at least on this account of rationality, rational to believe so or so it seems. Moreover, this gap can only be sustained if there is a plausible principle that permitted agents to refrain from considering all their evidence when deliberating about a proposition.

That said, in this case, no such plausible principle would permit Betty to not consider more of her evidence when she is, firstly, confronted with disagreement and, more importantly, failing to consider some crucial piece of evidence would lead to wrongful action. Betty failing to consider more of her evidence is irresponsible on her part. The point can be generalised: at least whenever there are moral stakes to a given question, it can be irresponsible and hence irrational to fail to consider salient and significant evidence. Another plausible principle is that when faced with disagreement we ought to consider all salient and significant evidence. After all, if Betty were to prescribe the treatment and then she is confronted with the fact that she failed to consider such evidence, it is hard to see how she could justify not considering said evidence. She could either blame herself, or provide some excuse, but either case would concede prior wrongdoing on her part in failing to consider said evidence[[14]](#footnote-14). If all this is right, in cases of shared evidence, if a proposition is not publicly justifiable, we are not in a position to know it. If we can still know a proposition in the face of disagreement, this must either be because the disagreement is not rational, or the rational disagreement would not persist if the disagreeing parties were suitably idealised.

Consider, now, the case where evidence is not shared. Clearly, there will be cases where people can rationally disagree when they have different bodies of evidence. However, not all of these cases will undermine knowledge. Suppose Alf has all the evidence regarding the riskiness of the treatment that Betty has and also some evidence that she does not. For instance, suppose Betty has access to a bunch of studies which, together, indicate not-TREATMENT. Alf has access to all these studies and also knows of an additional study which is really large and defeats the other evidence that Betty has. Plausibly, Alf can still know that TREATMENT is true even though Alf and Betty can rationally disagree. If this sort of disagreement undermined knowledge, then expertise and expert knowledge would not be possible. Even if Betty has evidence that Alf lacks, if Betty’s evidence, when added to Alf’s would not make a difference to what is justified for Alf, then Betty’s rational disagreement would not undermine Alf’s knowledge. We can imagine that Betty knows of another low-quality study or has some anecdotal evidence not available to Alf which on its own might suggest that not-TREATMENT. If this piece of evidence was added to Alf’s total body of evidence, he would still be justified in believing TREATMENT since his really good study would still defeat the new evidence.

However, such rational disagreement, which does not undermine knowledge, does not undermine public justification either. After all, these are clear instances where Betty’s body of evidence is strictly inferior to Alf’s. Public justifiability, on the other hand, requires no rational disagreement between *suitably idealised agents*. Suitably idealised agents are, among other things, not evidentially inferior.

To avoid evidential inferiority, Alf’s evidence for and Betty’s evidence against TREATMENT must be sufficient, but not decisive for belief. At the same time, Betty’s evidence must include some elements which are absent from Alf’s evidence and vice versa. We might imagine that Alf has access to many good studies, more of which suggest that TREATMENT is true. Meanwhile, Betty has access to many good studies, more of which suggest the opposite. Additionally sharing evidence would change what is justified for both agents. Here, we can imagine that at the minimum after sharing evidence with Betty, believing that the treatment is too risky is not uniquely justified for Alf. In such a situation, prior to sharing, both Alf and Betty can be justified in their respective beliefs. After all, their beliefs fit their respective bodies of evidence which they have not yet shared. Even if they know that there is someone out there who rationally disagrees with them, they do not know what evidence the other has and hence do not know whether evidential non-inferiority actually obtains.

However, rational disagreement under conditions of evidential non-inferiority will undermine knowledge even if agents are unaware that such conditions obtain. This is because even if knowledge is fallible, it cannot be so fallible that it persists in the face of defeaters that actually materialise. Since Betty’s evidence, when added to Alf’s at the very least makes either suspending judgment or disbelieving, in addition to believing, TREATMENT rational, Alf is not in a position to know that TREATMENT is true after acquiring Betty’s evidence. This makes Betty’s evidence a defeater for knowledge of TREATMENT. Even if knowledge does not require true beliefs to be indefeasibly justified, it does require that the defeaters never actually materialise. However, once people rationally disagree and evidential non-inferiority obtains, the defeater, or at least the materials for constructing a defeater, is in someone’s possession. Hence, nobody is in a position to know such propositions[[15]](#footnote-15).

**2.2.3 A Public Justification Requirement for Moral Demands**

The claim that moral demands are legitimate only if publicly justifiable follows logically from what we have argued so far. Knowing that Betty ought to φ is an achievement in that it involves eliminating a certain kind of risk that it would be wrong to take. Since rational disagreement by suitably idealised persons (i.e. a lack of public justification) would undermine knowledge, it is wrong to make a moral demand to φ if the claim that Betty should φ is not publicly justifiable. Since IRB decisions which restrict researchers involve making moral demands, IRBs may permissibly make such decisions only if those demands are publicly justifiable.

**3. Implications**

What does the public justification requirement mean in practice when applied to IRBs? At the most fundamental level, IRBs may require changes in the project proposal, request for more detailed information or delay or even stop the project only if no evidentially non-inferior person could rationally reject the demand. Where this condition does not hold, IRBs should allow the research to proceed.

This, of course, does not imply a complete *laissez faire* attitude towards regulating research. Instead, IRBs should demand only that researchers pick one of the available *reasonable* options. For instance, suppose that a proposed study has a size of 100 subjects, but the IRB determines this is underpowered based on an error in the study team’s power calculation. While all sufficiently informed parties would agree that the size is too small, they may disagree about how large the study should be, for example due to differing beliefs about the magnitude of an intervention’s effect that the study should be powered to detect. The IRB’s disagreement about exactly how large the study should be does not mean that they cannot make any demands on the researcher. Their disagreement masks their agreement that any sample size outside the range of reasonable options is too small. Hence, the belief that the IRB is permitted to demand that the study correct its error, and revise the sample size to anyone within that range is uniquely rational and true. At the same time, the IRB may to some extent defer to the study team concerning assumptions that went into determining expected effect sizes that determine the precise sample size needed to reach a statistically significant result, since there is reasonable disagreement about that.

The public justification requirement can also place constraints on what type of reasoning members of IRBs can engage in, when deliberating about a project. The argument given for the public justification argument here supports a convergence instead of consensus model of public justification (Gaus 2011, Vallier 2011). Therefore, while members of IRBs are not strictly forbidden from appealing to private or unshared reasons, they may not appeal to private reasons to justify a demand if others do not have access to other private reasons that would justify said demand.

The combination of these two implications means that an important task of IRBs is to determine whether a given disagreement is reasonable. We propose that one way to go about doing this is for IRBs to provide, to both researchers and the general public, explicit arguments in favour of their decision whenever the decision restricts researchers. This need not involve IRBs writing a full academic article defending each decision. However, it does require them to a) explicitly state the principles upon which the decision is made, b) adequately show how the proposal as it currently stands violates these principles and c) reference documentation that is to be made publicly available and shows these principles cannot be reasonably rejected. To accommodate convergence models of public justification, this documentation must show how the principles are supported by all the reasonable comprehensive doctrines that can be found in modern pluralist societies. Moreover, where one set of principles is reasonably rejectable, IRBs can also show that their decision is justified by multiple reasonable principles. Meanwhile, researchers who wish to dispute a decision must also be able to show that there is some reasonable moral point of view according to which the decision is not justifiable.

The point of such a system is not gratuitous essay writing, but to ensure that IRBs are in a position to know that a given research proposal is ethically unacceptable in its present form. In addition, the publicly available reference documents should also help researchers know why the IRB sets certain standards and why it requires certain kinds of information. This provides guidance in two ways. Firstly, it helps researchers work out the context in which the information is asked and allows them to better know exactly what information to provide. Secondly, it allows them to formulate in advance their objection to IRB requirements if they do disagree with it. A third upshot of a system like this is that it places some burden on IRBs to request changes to a proposal or block the proposal entirely, but no such burden to simply approve the study. Yet, the burden is not so heavy that, when a research proposal is clearly ethically unacceptable, or crucial information required to evaluate the proposal is genuinely lacking, IRBs are not able to exercise ethical oversight. Fourthly, making the justification and documentation publicly available allows for criticism by other bioethicists and IRBs. Mutual criticism allows IRBs to refine their arguments and brings them closer to only making publicly justifiable decisions. Fifthly making them public means that individual IRBs do not have to reinvent the wheel.

In practice, it is unlikely that everybody has distinct private reasons to endorse a given demand. Hence, most of the time, IRBs can permissibly make a demand on others if the demand can be justified on the basis of shared reasons. This requires a moral framework that expresses the common elements of any plausible moral theory. One example of such a framework is the set of 4 principles set out by Beauchamp and Childress. They claim that these principles are common to all moral frameworks. If they are indeed right about this, then whenever any of these 4 principles entail a demand, said demand is legitimate. Notably, use of the framework is asymmetric: private reasons can permissibly be invoked to reject a demand but not to justify a demand. However, in practice, reasons outside of the common moral framework rarely count *against* any given demand. Using the shared framework to reason about all decisions is, hence, unlikely to result in demands that are not publicly justifiable. As such, this asymmetry can be safely ignored in at least most cases.

To be clear, public justifiability, as we have used it in this paper, is a technical term. It is concerned primarily with the possibility of reasonable disagreement. It is distinct from the idea of acceptability to actual members of the public (Solomon 2016). Hence, while feasible implementations of publicly justifiable IRB decisions requires one form of transparency, namely the provision of undefeated reasons for decisions which restrict researchers, public justifiability does not commit us to others. For instance, no reasons need be produced to justify the decision to simply approve the study[[16]](#footnote-16). Neither does public justifiability require meetings to be open to the public or for the minutes to be publicly available. The question of whether acceptability applies to IRBs and to what extent it requires other forms of transparency is beyond the scope of this paper.

A consequence of the sharing of documentation and justification is that differences in standards between different IRBs will be easier to detect. This may facilitate efforts to improve IRB consistency and reduce uncertainty on the part of researchers concerning IRB expectations, as well as facilitate multi-site review.

There might, in addition, be a worry that local standards will inevitably give way to those of the wider public, especially when local standards are more stringent, forcing an artificial uniformity on all institutions. However, we can resist this worry in a number of ways. Which standards win out depends on the reason for the different standards. Sometimes, standards are different because the situation is genuinely different and morality has different requirements in different situations. Here, we can expect that the IRBs may not converge on similar standards since each can potentially be in a position to know what is morally required for their respective communities. Sometimes, local IRBs may be more inclined to reject a certain study simply because they hold a reasonable moral view, which nevertheless, is also subject to reasonable disagreement with the wider public. In such cases, the local standards should give way to the less stringent standards of the wider public. Sometimes, local standards are more stringent because the locals are in an evidentially superior position to the wider public on this issue. The weaker standards of the wider public are thus unreasonable. In that case, the public justification requirement would require the wider public’s standards to give way to local ones.

Another notable implication of the argument offered in the previous section is potentially significant: the public/private distinction is irrelevant. *All* IRBs are subject to the public justification requirement, not just public ones. How the public justification requirement bears on other aspects of our personal and social lives is a discussion best left to another paper.

**4. Contractual Obligations**

One significant objection here is that the public justification requirement has no bite because researchers, when they signed up for employment, may be contractually bound to abide by institutional policies, including policies on IRB approval. Since contracts are like promises and we cannot rationally reject the principle that we should keep our promises in most cases, IRBs would be permitted to demand that researchers abide by their decisions since they have made a prior agreement to do so. The problem with this objection is that it is unlikely that researchers actually count as promising to abide by the norms that IRBs set. Most universities, whether private or public, will have their own idiosyncratic moral norms, especially with the third type of oversight which is not linked to legal requirements.

As such, researchers may not be adequately informed about which norms the institution’s review board are likely to impose. Part of this is because IRBs cannot spell out in advance every moral norm they will impose. After all, there is no practical way to make obvious at the point of contract how exactly an IRB will instantiate decisions in the second and third type of case where the IRB decides which norms it will impose. Even when the IRB is only applying existing laws, it is unlikely that the contract includes information about all legal requirements. However, we can count as legitimately agreeing to do something only if we have a more or less concrete picture of what we are agreeing to do. Another part of this is because researchers, in practice, are unlikely to look through any long list of norms even if they could be specified in advance.

In addition, IRBs owe a justification for their demand not just to researchers but also to the wider public. While scientists do sign contracts, potential research participants do not. In making a demand that scientists refrain from conducting certain kinds of research, IRBs also demand that potential research participants do not participate in the research too. Since members of the public do not sign contracts prior to signing up as a research participant, demanding that they abide by publicly unjustifiable norms is impermissible.

**5. Conclusion**

What does this mean for the role of IRBs? Moore and Donnelly argue that because of deep moral disagreement, IRBs should abandon ethics review and stick to applying only those rules which are legislatively enacted because there is too much variation and unpredictability between the ethical norms different institutions will endorse. On the contrary, we have shown that when constrained by the public justification requirement, IRBs are well within their rights to make moral demands even in the face of (irrational) disagreement.

It should also be evident how public justification can feed into ensuring IRBs have a social license to operate. While this account is theoretical, in practice it limits how IRBs can operate when rational disagreement arises. In turn, this should limit the circumstances in which the public would morally object to the conduct of IRBs and thus undermine its social license. This does not completely remove the possibility that some will object to IRB decisions and authority, of course, nor addresses concerns that IRBs may in some instances be overly permissive. But it at least provides some foundation for bolstering the public acceptability of IRB actions in those cases where they limit what research can be conducted.

In addition, this framework provides further support for ongoing efforts to make IRBs more consistent in decision-making. If IRBs were to abide by the public justification requirement, they could have less variation without abandoning ethics review in its entirety. This is because abiding by a public justification requirement would likely require IRBs to act to restrict research primarily in cases where there is no rational disagreement over their demands. Presumably, it will be easier to achieve consensus and consistency over IRB judgments in cases where disagreement is not rational.

The preceding is primarily illustrative of how our account, while steeped in moral and political theory, has substantial practical implications for how IRBs should operate. Further research is needed to explicate the implications of our account, including fine-grained operational recommendations for IRBs. For now, we will simply conclude by noting that, though under-theorized, IRBs have a solid normative foundation to restrict research even when not empowered to do so by law – so long as their actions are publicly justifiable.

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1. Ted Dove made the same point during his keynote address in Australasian Association of Bioethics and Health Law Conference 2022 [↑](#footnote-ref-1)
2. The argument we provide in this paper is compatible with London’s (2022) defence of prospective ethics review. This parallels how public justification requirements and other arguments for limited governments are compatible with Hobbesian defences of the state. [↑](#footnote-ref-2)
3. i.e. All IRB decisions other than accepting a research proposal without comment. [↑](#footnote-ref-3)
4. Whereas some proportionality assessment with regards to risk to research subjects is required by The Common Rule, no such assessment is required by HBRA or NMRCA. Yet, IRBs in these jurisdictions still apply such an assessment. [↑](#footnote-ref-4)
5. See also the UK Medicines for Human Use (Clinical Trials) Regulation 2014. [↑](#footnote-ref-5)
6. For instance, Singapore and Australia [↑](#footnote-ref-6)
7. Certainly, IRBs are not the only entities which make moral demands. The issuing of moral demands is a central feature of moral life and plays a role in how societies are able to co-ordinate behaviour in the face of different preferences (Gaus 2011). This paper raises the example of IRBs, in part, because it is a particularly stark and formalised example of this practice. [↑](#footnote-ref-7)
8. Arguably also Leland and van Wietmarschen (2012). [↑](#footnote-ref-8)
9. In theory there could be epistemology boards which are convened purely to ensure that researchers maintain an adequate degree of epistemic hygiene. Presumably those boards may make purely epistemic demands on researchers. We do not comment on whether these demands are subject to a public justification requirement, only that ethics boards are. [↑](#footnote-ref-9)
10. While the question as to whether a given course of treatment is too risky is often going to depend on what alternatives there are and what their relative costs are, we will simplify our case by supposing that the only cause of disagreement between Alf and Betty on this issue is due to disagreement about exactly how risky the treatment is. [↑](#footnote-ref-10)
11. We focus on cognitive capacity-based accounts of permissivism in this paper instead of other accounts, for instance, those where different epistemic standards are justified in virtue of the agent’s different priors or epistemic risk attitude. We do this because for those accounts, it is easy to make the claim that the agent was lucky to have the right priors or epistemic risk attitudes which resulted in the justified belief being true. If the agent is lucky in those cases, then those cannot be instances of knowledge. Unlike those versions of permissivism, it is hard to argue that the mere luck of having been born with better cognitive capacities undermines knowledge. Cognitive capacities seem different from these other factors. [↑](#footnote-ref-11)
12. See Rosa (2012, 2016) for defences of a view like this. See also Anantharaman (2015) for an argument why such a view may not succeed. [↑](#footnote-ref-12)
13. We might think that he currently does not know because he is merely lucky that he did not encounter any sufficiently strong disconfirming evidence. Yet, given that believing that the treatment is too risky would still be justified even after considering all the evidence, there is no sufficiently strong disconfirming evidence. Hence it is not a matter of luck that his belief ends up true. Arguably, this is compatible with Betty being unlucky in failing to consider some sufficiently strong evidence that would disconfirm her belief. [↑](#footnote-ref-13)
14. For a more extensive discussion of this version of permissivism, contact the corresponding author for his manuscript, Permissivism and Epistemic Conservatism [↑](#footnote-ref-14)
15. One might object that in cases where Alf receives a genuine and transparently divine revelation that stem-cell research is wrong, he is in a position to know that it is wrong even if this claim is not publicly justifiable. However, evidential non-inferiority does not obtain in cases of true transparent divine revelation. Moreover, it would be prejudicial to idealise agents in such a way as to exclude religious views simply for being religious. After all, the claim that religious doctrines are not publicly justifiable is not a presupposition of the public justification requirement, but a distinct claim that political liberals make. Therefore, it would be publicly justifiable. In any case, third parties like IRB members are typically not in a position to adjudicate such claims as they would not be able to distinguish true divine revelations from false ones. [↑](#footnote-ref-15)
16. Although it might be prudent to keep records for audit purposes. [↑](#footnote-ref-16)