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Government Policy Experiments and Informed Consent

The Government of Ontario is currently running a three-year pilot project designed to evaluate a means-tested basic income policy (Government of Ontario, 2017). The participants are residents of three cities who are living with low incomes, and who have been randomly selected to apply. The basic income intervention will ensure that participants do not fall below a minimum level of income, $16,989 per year for a single person, and $24,027 per year for a couple. Participants with a disability will receive a further supplement of up to $500 per month. Participants will still be eligible for many of the benefits offered to low-income Ontarians – e.g. health insurance, child benefits, and dental benefits. The study will evaluate the effects of the basic income intervention on seven outcomes: food security, stress and anxiety, mental health, health and healthcare usage, housing stability, education and training, and employment and labor market participation.

Participants were enrolled in the study only after giving their informed consent; and one might think that the study would have been unethical absent this requirement. But consider that if the Government of Ontario simply *implemented* the basic income policy without securing residents' informed consent – i.e. as a legislative act – it is arguable that it would not have acted wrongly by doing so. After all, it is reasonable to think that legitimate governments have a right to make decisions about welfare policy, and there are strong arguments in favor of the claim that governments have a duty of justice to implement a basic income scheme (Van Parijs and Vanderborght, 2017). This

raises a puzzle: why is it permissible for the Government of Ontario to non-consensually subject residents to a basic income policy in the context of law-making, but impermissible for it to do so in the context of a pilot project?

Governments are increasingly making use of experiments such as these to evaluate policy interventions (Karlan, 2011; Banerjee and Duflo, 2012; Haynes *et al.*, 2012). However, the research ethics literature is largely focused on the clinical context, leaving investigators, Institutional Review Boards, and government agencies with few resources to draw on to address the ethical questions they face.[1] In this paper, we aim to help address this problem, investigating the conditions under which informed consent is required for ethical policy research conducted or authorized by government. We argue that investigators need not secure participants' informed consent when conducting government policy experiments if: (1) the government institution conducting or authorizing the experiment possesses a right to rule over the spheres of policy targeted by the research; and (2) data collection does not infringe participants' autonomy rights.

Our paper makes use of the rich history of ethical reflection on the role of informed consent in the clinical context with the hope of informing its appropriate use in the context of government policy experiments. Our analysis is particularly relevant to public health research since public health interventions are often the focus of government policy experiments, and since public health research often involves the use of cluster randomized trials where it can be impracticable to secure the consent of participants (Sim and Dawson, 2012).

In the first part of the article, we present what we take to be the most promising account of when it is permissible to conduct human subjects research without consent. In

the next section, we develop and modify this account for the context of government policy experiments. Subsequently, we consider how our ethical account of government experiments without consent should inform research regulations. Finally, we illustrate the implications of our account by considering a number of cases.

Research without Consent

In a recent article, Luke Gelinas, Alan Wertheimer, and Franklin G. Miller argue that research without consent is sometimes permissible (Gelinas *et al.*, 2016). According to Gelinas et al., the basic normative function of consent is to protect people's rights to autonomy or personal sovereignty (Gelinas et al., 2016, p. 36). On this account, competent adults have a right to autonomy, that is, a right to govern their lives in accordance with their values and preferences. Since many types of research – particularly biomedical research – are invasive, interfering with the sphere of action that is protected by the right to autonomy, investigators must secure the informed consent of participants for such research to be ethical. By consenting to specific research interventions, participants perform an act of self-government, rendering these interventions consistent with their right to autonomy. Informed consent is thus a morally transformative act, making an otherwise wrongful act rightful.

It is worth emphasizing here that on Gelinas et al.'s account, the role of consent in protecting and advancing participants' interests is secondary to that of protecting their rights to sovereignty or autonomy (Gelinas et al., 2016, p. 36). Consent can serve this former role since it allows people to decline interactions with others that promise to make them worse off. However, this role is secondary to that of protecting people's rights to

autonomy. As Gelinas et al. note, consent also enables people to accept interactions with others that promise to make them worse-off.

Gelinas et al.'s argument implies that consent is a necessary condition of the ethical conduct of many types of research; however, it does not show that it is necessary in all cases, particularly in cases where the research in question does not infringe people's autonomy rights. More specifically, Gelinas et al. argue that research without consent is permissible in two types of cases.

First, research without consent is permissible when it is: (1) impracticable to obtain consent; and (2) the research will not infringe the rights of participants (Gelinas et al., 2016, p. 36). The justification for (2) is that since the purpose of informed consent is to protect participants' rights to autonomy, if the proposed research does not stand to interfere with the sphere of action protected by these rights, consent is not necessary for the research to be permissible (Gelinas et al., 2016, p. 36). While (2) seems sufficient to justify research without consent, Gelinas et al. also stipulate that (1) is also a necessary condition. While the principal justification for consent is the need to respect people's right to autonomy, Gelinas et al. argue that consent promotes "transparency and trust in the research enterprise" (Gelinas et al., 2016, pp. 36). It is prudent, they therefore argue, to only permit research without consent in cases where obtaining consent is impracticable, that is, when obtaining consent is either too costly in terms of time or money, or when it threatens the scientific validity of the study, for example, through the introduction of certain forms of selection bias (Gelinas et al., 2016, p. 36).

Gelinas et al. also argue that research without consent is permissible when: (1) it is impracticable to obtain consent; (2) the infringement of participants' rights is minor;

and (3) the expected social value of the research is sufficient to outweigh the infringement of rights (Gelinas et al., 2016, pp. 36-37). The idea here is that rights are not absolute and so that an infringement of people's rights, though pro tanto wrong, can be outweighed by competing considerations, for example, the production of socially valuable knowledge.

Gelinas et al. claim that a number of types of human subjects research may satisfy these conditions for research without consent (Gelinas et al., 2016, p. 37).[2] Of particular interest given our focus on government policy research, Gelinas et al. claim that quality improvement research – i.e. studies evaluating the effectiveness of interventions aimed to improve practices within institutions such as hospitals or clinics – may be carried out without consent (Gelinas et al., 2016, p. 37). Provided that the institution in question is evaluating an intervention within a sphere of action over which it has legitimate control, such research does not infringe the rights of the institution's clients (Gelinas et al., 2016, pp. 37-38). For example, Gelinas et al. claim that a hospital has the right to conduct research on the effectiveness of two types of disinfectant soap without patient consent (Gelinas et al., 2016, p. 37).

In our view, Gelinas et al.'s account of when research without consent is permissible is the most promising on offer. Although Gelinas et al. are largely concerned with the question of the ethics of research without consent in *clinical* contexts, their justificatory framework also has lessons for government policy experiments. Indeed, as will become clear below, the relation of institutions to their clients in the context of quality improvement research is similar in many ways to the relation of government to its residents.

Before turning to the context of government policy experiments however, we want to identify what we think is a questionable move within Gelinas et al.'s argument. As we note above, Gelinas et al. defend the impracticability condition on the grounds that "in general, obtaining consent helps to promote transparency and trust in the research enterprise" (Gelinas et al., 2016, p. 36). It is important to recognize that this is a different type of argument than the argument they give for the no rights infringement requirement. The argument for the latter requirement is that informed consent is necessary to render invasive research interventions consistent with participants' autonomy rights. Consent thus functions as a morally transformative act, rendering an otherwise wrongful act rightful. The argument for the impracticability condition, by contrast, is an instrumentalist one, claiming that informed consent tends to be an effective means for realizing some goods, in this case, transparency and public trust in the research enterprise.

Because the argument for the impracticability condition takes this form, we think it is a mistake to claim that this condition is a necessary condition of permissible research without consent. While we agree that transparency and public trust in research are goods that investigators have a duty to promote, we see no reason to think that informed consent is necessary as a means to realize these goods. With respect to public trust, whether an experiment without consent that meets the no rights infringement condition but not the impracticability condition has an effect on public trust is an empirical matter. A trial may have no negative effect on public trust in the research enterprise and so it does not make sense to make the impracticability condition a necessary condition of permissibility. In addition, there may be other means to secure public trust in research other than informed

consent. With respect to transparency, if the goal is to inform participants on the nature of the experiment in which they are enrolled, this can be achieved through means other than informed consent, for example, publication of the materially relevant features of the experiment.[3]

At most, what follows from Gelinas et al.'s argument for the impracticability condition is that there may be prudential reasons in favor of it, namely, that including the impracticability condition will lead to greater transparency and public trust than would otherwise be the case. This is not nothing, as it gives policymakers a reason to include the impracticability condition in regulations governing research. Indeed, as we discuss below, we largely agree with Gelinas et al. that there are good prudential reasons to include the impracticability condition in research regulations. But, we don't think it shows that this condition is a necessary condition of the *ethical permissibility* of research without consent. By contrast, the no rights infringement condition *is* such a condition (or is at least a necessary condition of research that is not pro tanto wrong). If research interventions involve infringement of competent people's autonomy rights, informed consent is the only way to ensure that no wrong is committed.

Gelinas et al. seem to recognize the force of this objection elsewhere in their article. They note that informed consent not only serves to protect people's autonomy, but also to "protect and advance the interests of prospective research participants." (Gelinas et al., 2016, p. 36). However, Gelinas et al. do not understand this to be a consideration in favor of the impracticability condition since they recognize that it is sometimes permissible to set back an individual's interests without their consent. As they put it,

> The most basic function of consent is to waive rights of control, allowing others to interact with us in ways that would otherwise be wrong. Consent is needed when, and only when, interactions stand to wrong one of the parties involved, by violating their personal sovereignty or rights of control (Gelinas et al., 2016, p. 36).

What we have tried to show above is that this point also speaks against their argument in favor of the impracticability condition. The fact that informed consent promotes a number of goods – e.g. transparency, public trust in the research enterprise, and the promotion of participants' interests – does not imply that it is a necessary condition of the permissibility of ethical research, and so does not support the impracticability condition.

In the following section, we develop Gelinas et al.'s framework for the context of government policy experiments. However, in light of our discussion here, we drop the impracticability condition, at least as it concerns the question of the ethical permissibility of research without consent, and not the question of the design of research regulations. We return to the impracticability condition later in the paper when we discuss the shape that research regulations ought to take.

Government Policy Experiments without Consent

Our aim in this part of the paper is to specify the conditions under which governments may conduct policy experiments without consent. By a *policy experiment* we mean the introduction of a policy intervention, or the alteration of an existing policy intervention, as part of a systematic investigation having the aim of generating knowledge about the intervention's impact. Policy experiments are thus different from

observational research concerning the effectiveness of existing policy interventions. The former, unlike the latter, involve an experimental component – i.e. the introduction of a research intervention. By *government* policy experiments, we mean policy experiments that are either conducted by a government agency, or authorized by a government agency, for example, when a non-government actor contracts with, or is granted permission by, a government agency to introduce and evaluate a policy intervention.

We begin by specifying the implications of Gelinas et al.'s justificatory framework – minus the impracticability condition – for the context of government policy experiments, arriving at a preliminary conclusion regarding the permissibility of government policy experiments without consent. We then offer two refinements to this preliminary conclusion, arriving at a more precise statement of the conditions under which government policy experiments without consent are permissible. Our analysis in this section of the paper is an exercise in ideal theory; we therefore presuppose that agents comply with the ethical norms and principles that apply to them.

Implications of Gelinas et al.'s Justificatory Framework

As we note above, Gelinas et al. specify two sets of conditions under which research without consent is permissible. The first set governs cases where research does not infringe people's rights; the second set governs cases where research does infringe people's rights. While we largely accept both sets of conditions, we bracket the second set here as we don't think it requires much modification or comment for application to the context of government policy research. We agree that rights are not absolute and so may be infringed when the benefits of doing so are great, and the infringement minor.

With respect to the first set of conditions by contrast, some work is necessary to identify when government action infringes residents' autonomy rights and when it does not.

Gelinas et al.'s first set of conditions hold that research without consent is permissible when: (1) obtaining consent is impracticable; and (2) the research will not infringe the rights of participants. Setting (1) aside, we suggest that (2) has far-reaching implications. The reason for this is that it is reasonable to think that residents do not have *autonomy* rights over government policy making. The right to autonomy clearly places *limits* on government policy making – the purpose of basic rights and liberties such as freedom of expression, freedom of association, and freedom of religion, is to protect from state intervention a sphere of action in which individuals ought to be sovereign. However, many scholars quite reasonably claim that legitimate states possess a *right to rule* over many spheres of action, that is, a claim right to enact the laws and policies that govern residents' behavior. Residents of these states, these scholars argue, have a corresponding content-independent obligation to obey the laws and policies their government enacts (Rawls, 1996, pp. 136-137, 427-429; Waldron, 1999, pp. 101-118; Wellman, 2001; Klosko, 2005; Christiano, 2008).

Scholars disagree on the conditions states must satisfy to be legitimate and so have a right to rule. Some argue that states are only legitimate if residents *consent* to the state's rule, a view that implies that no existing states are legitimate (Simmons, 1999). Others, by contrast, argue that it is enough that political power is exercised in accordance with institutional procedures that are sufficiently democratic (Pettit, 2012) or justifiable to those subject to it (Rawls, 1996, pp. 136-137). Still others deny that states can be legitimate (Wolff, 1970; Huemer, 2013).

Resolving these debates is of course beyond the scope of this paper. However, we shall proceed on the assumptions that some proceduralist conception of legitimacy is defensible, and that many existing liberal democracies satisfy this conception, implying that they possess a right to rule. On this view of the government-resident relation therefore, governments and their residents possess mutually exclusive spheres of sovereignty. Individual residents are legitimately sovereign over those spheres of action protected by their right to autonomy; and governments are legitimately sovereign over those spheres of action protected by their right to rule. Provided they respect the limits of their right to rule, governments do not therefore infringe their residents' rights to autonomy by engaging in policy making.

This does not mean that governments may act in any way that they please. Governments have duties of justice to their residents and so ought only to enact and enforce laws that are just. So, although legitimate governments have a right to rule, and so a right to enact laws and policies that are less than fully just, they ought to enact laws and policies that are fully just.

Some would no doubt find it surprising that governments possess a right to rule and that this right can be consistent with residents' rights to autonomy. After all, many actions of government can be understood to "invade people's autonomy." For example, governments regulate the types of substances residents may put in their bodies through criminal prohibitions on drugs, and safety regulations on foods and pharmaceuticals; governments regulate how residents may treat each other through criminal prohibitions on various forms of violence and abuse; and governments regulate the types of contracts

residents may agree to through prohibitions on the purchase of sexual services and labor regulations.

In response, note that the claim here is not that governments never regulate what we do with our bodies, but rather that individuals do not possess a *right* to exercise their bodily capabilities in any way that they please, free of government interference. Instead, there are certain types and aspects of our bodily action that government possesses the right to govern – i.e. to specify the rules individuals must obey. For example, government has the right to prohibit certain forms of interpersonal violence, and so laws prohibiting murder and assault do not infringe residents' autonomy rights.

It is beyond the scope of this paper to delineate the precise scope of governments' right to rule. However, on the assumptions that governments possess this right, and that it extends over the typical functions of contemporary liberal democracies, a good deal of government policy making does not infringe residents' autonomy rights. This conclusion is important for our purposes since it follows from this that on Gelinas et al.'s justificatory framework, a good deal of government policy experimentation may not require participants' informed consent. With respect to those spheres of action protected by governments' right to rule, governments can subject residents to experimental policies without infringing residents' autonomy rights. In these cases, it would seem to follow that investigators carrying out government policy experiments need not obtain participants' informed consent.

The normative relation of governments to their residents is thus similar to the relation that Gelinas et al. understand to obtain between clinical institutions – e.g. hospitals – and their patients. Recall that for Gelinas et al., clinical institutions possess a

"right of control" over certain spheres of institutional action. This entails that patients possess no right to autonomy over these spheres of action, and so that clinical institutions do not infringe their patients' autonomy by engaging in quality improvement research regarding policies governing these spheres of action. Similarly, governments have a right to rule certain spheres of action and so research on interventions pertaining to such spheres of action does not infringe residents' autonomy rights. To return to Ontario's basic income pilot project, provided Ontario possesses the legitimate authority to govern welfare policy, it would not need to secure Ontarians' informed consent to participate in the pilot. The Government of Ontario is entitled to decide on the design of welfare policy, and so it does not necessarily infringe residents' autonomy rights by designing it in one way rather than another.

One might object that residents *do* have rights to autonomy that extend over government policy making. Citizens, and perhaps all persons subject to a government's rule, one might argue, have rights to participate in the political process. As such, government must secure the informed consent of the governed prior to enacting any law or policy or evaluating any law or policy in the context of a study.

There is some truth to this objection. On many proceduralist accounts of legitimacy after all, the granting of political rights to citizens is a necessary condition of a government's legitimacy, a condition that is important for the question of research without consent. However, there is an important distinction between autonomy rights and political rights, at least as the latter are typically understood. A person's right to autonomy implies that she has a veto over any interference by another agent in the sphere of action over which she is sovereign. By contrast, a person's political rights – e.g.

freedom of expression, the right to vote, and the right to run for public office – only secure for her a right to participate in the political process. As such, they do not grant her a veto over legitimate law and policy making: within its sphere of legitimate sovereignty, government may legitimately subject its residents to laws and policies to which they explicitly object. For example, the fact that one objects to the passing of a sales tax does not imply that one has no obligation to pay it. More generally, if political rights were simply autonomy rights, governments would only be entitled to enact a law or policy if all citizens consented to its passage – i.e. it would entail *unanimous direct democracy*.[4]

One might grant that legitimate governments possess a right to rule over many spheres of residents' lives for the purposes of creating a just society and promoting residents' wellbeing, but not for the purposes of research – i.e. producing generalizable knowledge. Legitimate governments, one might think, have a right to impose education policies on their residents, provided the purpose of doing so is to educate them; however, they don't have a right to impose education policies on their residents for the purposes of producing generalizable knowledge regarding the effectiveness of particular education policies.

This view is implausible. If it were true that the production of generalizable knowledge was outside of the sphere of legitimate government policy-making, it would follow that governments would act wrongly by conducting pilot projects or funding academic and applied research. Governments may use their right to rule to produce generalizable knowledge, we would suggest, because such knowledge is often necessary if governments are to fulfill their obligation to create a just society and promote residents' wellbeing. Policy research in particular is an important means by which legitimate

governments realize these purposes: it is the means by which governments determine which policy interventions will enable it to most effectively promote residents' wellbeing and fulfill their mandate of creating a society in which all residents receive the goods, services, and outcomes – e.g. health and education – to which they are entitled.

One might argue that policy experimentation is objectionable because it involves experimenting on existing residents for the benefit of future residents.[5] But note that there is arguably nothing wrong with governments exercising their right to rule in ways that benefit future residents but not current residents. Governments have obligations to future residents as well as current residents, and so it is permissible for them to exercise their right to rule in ways that promote the interests of the former but not the latter. For example, it is permissible for governments to enact a variety of policies to limit the effects of climate change – e.g. a carbon tax – even though such policies may impose net costs on many current residents. Even if governments have no duties to future people moreover, many – if not most – policy experiments will also benefit existing residents.

Legitimate governments may therefore use their right to rule to facilitate the production of generalizable knowledge. Gelinas et al.'s justificatory framework therefore has wide-ranging implications for government policy experiments. On the assumption that governments possess a right to rule over certain spheres of action, governments do not infringe their residents' autonomy rights by subjecting them to policy interventions either as a matter of legislation, or in the context of policy research. We therefore arrive at the following preliminary conclusion:

Informed consent is not a necessary condition of ethical government experimentation research if government possesses a right to rule over the spheres of action targeted by the research.

This conclusion is preliminary since we think it requires a good deal of development and qualification. We tackle this task next.

Refining the Preliminary Conclusion

According to the preliminary conclusion therefore, informed consent is not necessary in all circumstances for the ethical conduct of government policy experimentation. In this section of the paper, we offer two refinements to this conclusion. The first concerns other aspects of policy experimentation – other than the subjection of a participant to an experimental policy – that may require informed consent. The second aims to flesh out the notion of *governments' right to rule*, given that governments are not unitary agents.

The principal justification for the claim that governments may sometimes conduct policy experiments without consent is that governments possess a right to rule over certain spheres of action, and so do not infringe the autonomy rights of their residents by subjecting them to particular policy interventions whether as legislation or in the context of research. However, policy research involves more than simply the subjection of residents to one or more interventions. Investigators must also collect data concerning the effects of the research interventions on outcomes of interest. For some interventions, the data in question may be publicly accessible, or may be data that government is entitled to collect. For others however, collection of the relevant data may require the infringement

of people's autonomy rights. For example, if government wishes to evaluate differing lead abatement strategies, investigators may need to conduct blood draws on residents, or visit homes to test for lead content to determine the effectiveness of these strategies. Similarly, if government wishes to evaluate differing approaches for promoting income and food security, investigators may need to acquire fairly private information from households affected by the interventions under study, for example, information on how households are spending their money.

Where data collection can only proceed through an infringement of people's autonomy rights, it will not be permissible for governments to conduct the research without securing people's informed consent, if only to the collection of the data in question. For this reason, we need to add a second condition to our preliminary conclusion:

> Informed consent is not a necessary condition of ethical government policy experimentation if:
>
> 1. Government possesses a right to rule over the spheres of action targeted by the research; and
> 2. Data collection does not involve the infringement of participants' autonomy rights.

A second refinement to the preliminary conclusion is also necessary, one that concerns our understanding of government and its right to rule. Thus far, for purposes of simplification, we have spoken of government as though it is a unitary agent. Things are of course more complex. In federations, sovereignty is split between two or more levels of government having independent grounds of authority (Bednar, 2008, pp. 18-19). In

many if not most countries, government is also divided into different branches: legislative, executive, and judicial. These branches themselves have sub-units possessing differing powers and levels of authority.

Research is thus never conducted by *government* but is instead carried out or authorized by some particular agent or institution within government. This matters since different agents and institutions within government have differing levels and types of legitimate authority. Thus, when we say that government has the right to rule over some sphere of policy, what we really mean is that some particular government institution has the right to do so. Thus, the US Congress has the right to pass laws governing the health care industry, while the Department of Health and Human Services has the right to issue regulations to implement these laws. We must therefore revise our preliminary conclusion in the following way:

> Informed consent is not a necessary condition of ethical government policy experimentation if:
>
> 1. The government institution conducting or authorizing the research possesses a right to rule over the spheres of policy targeted by the research; and
> 2. Data collection does not involve the infringement of participants' autonomy rights.

This is an important revision for it places a restriction on the agents within government that may carry out or authorize certain types of research without consent. For example, we may think that the US Congress has the right to enact laws regarding the health care industry because US citizens have democratic rights and so some form of control over

how the US Congress exercises its legislative power. If this is so, it would be permissible for the US Congress to authorize a pilot project evaluating certain changes to existing legislation but may not be permissible for the Department of Health and Human Services to do so.

Determining whether a particular government agent possesses a right to rule will of course be a difficult matter, requiring the consideration of a number of complex normative and empirical factors. However, as a useful rule of thumb we might note that if a government institution or agent does not have the authority to enact a law or policy with respect to a particular sphere of policy, it probably does not have the authority to subject residents to an experimental intervention in the context of policy research (unless that intervention has been authorized by the body with the relevant law or policy making authority).

Governments may therefore conduct or authorize policy experimentation without informed consent when the above two conditions are satisfied. When these conditions are satisfied, investigators need not secure participants' informed consent since the research in question does not infringe their autonomy rights.

As we note above, we also agree with Gelinas et al. that research without consent is sometimes permissible even when participants' autonomy rights are infringed. The general point here is a familiar one that applies beyond the sphere of research ethics: it is sometimes permissible to infringe people's rights when the infringement is minor and promises a significant benefit. To the above set of conditions of when government policy experimentation without consent is permissible, we would therefore add that it is also permissible when: (1) it is impracticable to obtain consent; (2) the infringement of

participants' rights is minor; and (3) the expected social value of the research is sufficient to outweigh the infringement of rights (Gelinas *et al.*, 2016, pp. 36-37). In cases such as these, although investigators commit a pro tanto wrong against participants, this wrong is outweighed by the amount of good that the research is expected to yield.[6]

One might argue that the focus of our framework is too narrow. By focusing on the question of when it is permissible for government investigators to subject residents to a policy experiment without their consent, we are missing an ethically relevant feature of many policy experiments, namely, the random allocation of participants into treatment and control arms. One might argue that such randomization involves governments treating residents unequally, offering a potentially beneficial treatment to some, but not to others. For example, in the process of designing and implementing its basic income experiment, the Finnish government was constrained by the Constitution of Finland's commitment to equal treatment ('Northern Pilot,' 2017).[7] More broadly, one might argue that by allowing government policy experimentation to proceed without consent when either set of the above sets of conditions is satisfied, we are opening the door to government abuse and/or exploitation of research participants.

In response to the first objection, we agree that the random assignment of residents to either treatment or control arms raises important questions of fairness and equality. However, we disagree that informed consent offers the best solution to such questions. To ensure that random assignment is consistent with governments' duty to treat residents equally, we follow Douglas MacKay in holding that government investigators must ensure that randomized controlled policy experiments comply with the principle of "policy equipoise" (MacKay, 2018). According to this principle,

governments may only conduct or authorize a randomized controlled policy experiment if all arms of the experiment are in a state of equipoise with the policy to which residents are entitled to be subject (MacKay 2018, pp. 62-63). For experiments that satisfy this principle, participants may be randomly assigned to different policies and so receive different benefits, however, there will be reasonable disagreement within the expert social scientific community about which policy is better for participants. This principle therefore directly addresses the above-mentioned problem regarding randomization since compliance with it ensures that participants are treated equally by government investigators.

In response to the second objection, just as informed consent is not the only ethical requirement for biomedical research, so too it is not the only ethical requirement for government policy experimentation. Even if a government-conducted pilot project satisfies either of the above-mentioned sets of conditions and so investigators need not secure participants' informed consent for it to be ethical, the study must surely satisfy other ethical norms and principles – e.g. MacKay's principle of policy equipoise but also the principle of beneficence. Moreover, since this section of our paper is an exercise in ideal theory, we presuppose that investigators carrying out government policy experiments will comply with these other norms and principles. At least under ideal circumstances therefore, informed consent is not necessary as a "last line of defense" for participants, for example, because investigators cannot be trusted to comply with other principles and practices designed to protect participants – e.g. to conduct a rigorous risk-benefit analysis. In the next section of this paper, we relax this presupposition and consider how our account should be realized in the context of the (non-ideal) real world.

Regulations for the Non-Ideal World: The Return of the Impracticability Condition

Our account outlines the conditions under which it is permissible for governments to conduct policy experiments without the consent of their residents. When these conditions are satisfied, informed consent is not a necessary condition of ethical research. Our analysis follows Gelinas et al. in proceeding on the assumption that the "most basic function" of consent is to respect people's autonomy rights (Gelinas et al., 2016, p. 36). However, as Gelinas et al. and other scholars argue, consent can perform additional valuable functions. Under ideal circumstances, where investigators comply with the principles and duties that apply to them and people act reasonably, these functions can be performed by other principles and practices. Under non-ideal circumstances however, we think it is prudent to build redundancy into any system of regulations designed to protect research participants and the sustainability of the research enterprise itself. Hence, as a matter of regulatory design, for government policy research that does not infringe participants' autonomy rights, we think the impracticability condition should be added to the set of conditions we outline above.

First, as Gelinas et al. argue, informed consent helps to promote the goods of transparency and public trust in the research enterprise (Gelinas et al., 2016. p. 36). The informed consent process can help participants understand the nature of the experiment they are participating in and can help head off public outcry about the treatment of research participants. For example, setting aside issues of data collection, on our account it is permissible for the Government of Ontario to enroll low-income Ontarians into its basic income pilot project without their consent. However, if investigators conducted the

experiment in this fashion, it is possible that people would argue that participants were being treated like "lab rats" and that this sentiment could spread widely enough to diminish public support for the current project and future government policy research.

More generally, Neal Dickert et al. have recently argued that consent processes serve six functions in addition to protecting participants' autonomy rights: "providing transparency;" "promoting concordance with participants' values;" "protecting participants' welfare interests;" "promoting trust;" "satisfying regulatory requirements;" and "promoting the integrity of research and researchers" (Dickert *et al*., 2017, p. 4). We would suggest that under ideal circumstances, consent processes are not *necessary* to promote these goods to the degree that is ethically required. For example, in the context of government policy experimentation, a rigorous risk-benefit assessment and compliance with the principle of policy equipoise is sufficient to protect the welfare interests of participants. However, in the non-ideal world of regulatory design, we think it is wise to build in some redundancy. Thus, while informed consent is not *necessary* under ideal conditions to ensure that government policy experimentation is ethical in cases where it does not infringe participants autonomy rights, in the real-world context informed consent may help ensure that government policy research is as ethical as possible by performing some or all of the above-mentioned functions. In particular, it offers an extra mechanism, alongside a risk-benefit assessment, to protect the interests of participants; and it can help promote certain goods such as transparency and public trust in the research enterprise.

For these reasons, we think that Gelinas et al.'s impracticability condition should be added to our account for the purposes of guiding the design of research regulation.

While not strictly speaking necessary to ensure that government policy experimentation is ethical, the addition of this condition helps ensure that real-world government policy experimentation adequately protects the interests of participants and promotes research-related goods. Our regulation-relevant account of government research without consent is therefore as follows:

> Informed consent is not a necessary condition of government policy experimentation if either conditions 1-3 or conditions 3-5 are satisfied:
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> 1. The government institution conducting or authorizing the research possesses a right to rule over the spheres of policy targeted by the research.
> 2. Data collection does not involve the infringement of participants' autonomy rights.
> 3. Obtaining consent is impracticable.
> 4. The infringement of participants' rights is minor.
> 5. The expected social value of the research is sufficient to outweigh the pro tanto wrong of a minor infringement of participants' rights.

Following Gelinas et al., we suggest that obtaining consent can be impracticable for two distinct reasons. First, obtaining consent can be impracticable when it is too costly in terms of time or money. Determining how much cost is too much of course requires careful judgment; however, as a rule of thumb we would suggest that the cost of obtaining consent is too much in cases where it would threaten the ability of investigators to carry out the study or the ability of government to carry out similarly valuable projects. For example, some policy experiments may involve hundreds of thousands of participants spread out across vast geographical distances. Obtaining consent in these experiments

may be prohibitively expensive – on our rule of thumb – even for middle- or high-income governments. The second reason that obtaining consent can be impracticable is when it threatens the scientific validity of the study through the introduction of certain forms of bias (Gelinas et al., 2016, p. 36). For example, the Government of Finland decided to make participation in its basic income experiment mandatory on the grounds that voluntary participation would introduce selection bias (Kela 2016, 11-12).

In our view, this addition of the impracticability condition nicely realizes two imperatives for any set of research regulations. First, it adds an extra mechanism for realizing some or all of the above-mentioned goods by requiring informed consent in cases where it is practicable for investigators to secure it. Second, it does not unduly burden researchers or forbid potentially valuable research insofar as it permits research without consent when securing consent is impracticable and the research poses no serious threat to participants' autonomy rights.

Cases

In this part of the paper, we apply our regulation-relevant account to some real-world cases. Our aim here is not to render a final judgment regarding the moral permissibility of these experiments, or even to determine definitively whether consent is a necessary condition of their ethical conduct. Our aim instead is to: (1) show that our account can yield reasonable conclusions; and (2) demonstrate how investigators, policy makers, and members of research ethics committees can use our account to determine if consent should or should not be required in the context of a particular experiment.

The State of Tennessee's Student/Teacher Achievement Ratio (STAR) Project

In May of 1985, the Tennessee Legislature authorized and funded a randomized controlled trial (RCT) to determine the effects of class size on student achievement in grades K-3 (Word *et al*, 1990, p. 1). The Tennessee State Department of Education planned and conducted the study in cooperation with researchers from Memphis State University, Tennessee State University, the University of Tennessee at Knoxville, and Vanderbilt University (Word *et al*, 1990, p. 2). All Tennessee public school systems were invited to participate in the study, though schools had to agree to the random assignment of teachers and students to different class conditions (Word *et al*, 1990, pp. 5-6). Beginning in August 1985, 79 schools in 42 systems participated in the study, with students and teachers randomized to 128 small classes (13-17), 101 regular classes, and 99 regular classes with teacher aides (Word *et al*, 1990, p. 6). 22 schools were also used as comparison schools, and students in these schools were given the same tests as students in the 79 Project STAR schools (Word *et al*, 1990, p. 6). All student participants in STAR received no fewer services than non-participants, and STAR did not require any changes to participating schools – e.g. curriculum or schedule (Word *et al*, 1990, p. 8). The study ran for 4 years, and data were collected for students, teachers, principals, teacher aides, schools, and school systems (Word *et al*, 1990, p. 8).

Although representatives of Tennessee school systems had the opportunity to consent to participate in the study, most participants – i.e. principals, teachers, teachers' aides, and parents (on behalf of students) – did not. In our view, this is not a problem: Project STAR clearly satisfies conditions 1-3 of our account.

First, the study was authorized by the Tennessee Legislature which clearly had the authority to determine class sizes in public schools, thus satisfying condition 1. State legislative bodies are widely understood to have the legitimate authority to enact policy regarding class sizes in public schools. Second, condition 2 was also satisfied since the data collection practices employed in the study were no different from those practices employed as a matter of course in Tennessee public schools – e.g. measures of student achievement, profiles on schools, school systems, principals, and teachers, and observations of teacher and teacher aide activities. Finally, obtaining the consent of principals, teachers, teacher aides, and parents would have been impracticable, potentially requiring a sizeable reassignment of principals, teachers, teacher aides, and students to ensure that there were schools in which there was a sufficient number of participants for the study to occur. Such a reassignment may also have threatened the external validity of the study, creating schools with populations unlike existing schools. Condition 3 was also therefore satisfied (Word *et al*, 1990, pp. 16-17).

The Healthy Incentives Pilot

The Supplemental Nutrition Assistance Program (SNAP) is the principal nutritional assistance program in the U.S. Recipients receive an electronic benefit transfer (EBT) card with which they may purchase a wide variety of foods. In 2011, the U.S. Department of Agriculture's Food and Nutrition Service designed the Healthy Incentives Pilot (HIP), a pilot project aimed at determining whether SNAP recipients would increase their consumption of fruits and vegetables if they were given financial incentives to do so (Bartlett et al., 2014, p. 1). Under the HIP, participants received an incentive of $0.30 on

their EBT card for each dollar of SNAP benefits they spent on targeted fruits and vegetables in participating retailers. The HIP was implemented in late 2011 by the Massachusetts Department of Transitional Assistance in Hampden County and continued until the end of 2012. Through the Food, Conservation, and Energy Act of 2008, the U.S. Congress explicitly authorized funds for pilot projects to determine if SNAP recipients would increase their consumption of fruits and vegetables and other healthful foods in response to incentives (Bartlett et al., 2014, p. 11).

7,500 SNAP recipients in Hampden County were randomly selected to participate in the HIP pilot, receiving multiple notifications of the pilot and specially marked EBT cards (Bartlett et al., 2014, p. 25). The remaining 47,596 eligible SNAP households did not receive the HIP incentive. HIP participants did not consent to participation in the study. Indeed, despite receiving multiple notices regarding HIP, only 62 percent of HIP households reporting having heard of HIP 4-6 months after they began participating in it (Bartlett et al., 2014, p. 85). Data were collected from a variety of sources, including through voluntary surveys with samples of both HIP and non-HIP households, from EBT transaction data, and from surveys and observations of participating food retailers (Bartlett et al., 2014, pp. 26-38).

The HIP clearly satisfies conditions 1-3. First, the U.S. Congress has the legitimate authority to make decisions regarding the structure of SNAP, and clearly authorized a pilot project to test the effectiveness of financial incentives. Second, data collection occurred either through voluntary processes – e.g. telephone surveys – or from sources accessible to the Food and Nutrition Service as a matter of course – e.g. EBT transaction data.

Finally, it is reasonable to think that securing the consent of HIP participants would have been impracticable. A central research objective of the study was to "Assess the causal impact of HIP on fruit and vegetable consumption by SNAP participants, and on other key measures of dietary intake" (Bartlett et al., 2014, p. 13). A requirement of informed consent would have arguably prevented the Food and Nutrition Service from realizing this objective. First, the requirement of informed consent would have introduced problems of selection bias since SNAP recipients willing to participate in the HIP may be different from those who are not. Second, the requirement of informed consent would have changed the intervention in an important way. Investigators wanted to know if the HIP intervention would impact people's consumption choices in the real-world context – i.e. as a revision to SNAP. It was therefore important to ensure that the roll-out of the intervention in the context of the study mimicked how it would be rolled out as a policy change. If the Food and Nutrition Service decide to implement the HIP intervention as a revision to SNAP, they would not seek the informed consent of all SNAP recipients prior to doing so but would instead simply notify SNAP recipients of the change. It was thus important for investigators to test the impact of the HIP intervention under similar conditions.

Indoor Residual Spraying in Pakistan

In June 1997, investigators conducted a cluster randomized controlled trial in a large area of Punjab province in Pakistan with the aim of determining the efficacy of a new insecticide in reducing the incidence of falciparum and vivax malaria (Rowland *et al*., 2000). The 180km^2 study area was divided into nine sectors, encompassing 60

villages, and each sector was assigned at random to receive no treatment, a wettable powder form of the new insecticide alphacypermethrin, or a suspension concentrate form of this insecticide (Rowland *et al*., 2000, pp. 472-473). Both forms of the insecticide were administered through the use of spray pumps, and more than 95% of compounds – i.e. living quarters, storage rooms, and animal shelters – were sprayed (Rowland *et al*., 2000, p. 473). Approximately 2000 people in each of the nine sectors were followed up on for a number of months, with blood smears taken from any household member reporting a fever during the previous 3 days, amongst other forms of monitoring (Rowland *et al*., 2000, p. 473). Village elders consented to the study, but individuals did not (Rowland *et al*., 2000, p. 273). The field study was funded by Cyanamid, an American corporation, received technical support from the World Health Organization Pesticide Evaluation Scheme, and was led by investigators from HealthNet International, the London School of Hygiene and Tropical Medicine, and Pakistan's National Institute of Malaria Research and Training (Rowland *et al*., 2000, p. 480). The involvement of staff from the latter organization suggests that the study was authorized by an agency of the Pakistani government.

This cluster randomized trial clearly satisfies condition 3 since it would have been very costly to secure the consent of the tens of thousands of villagers living within the study area. Requiring consent would also, arguably, undermine the purpose of the study which was to determine the efficacy of spraying *all* compounds within a designated area. It's unclear if the study satisfies condition 2. Data collection involved blood smears from individuals who reported having a fever; however, the published account of the study is not clear on whether consent was sought from the individuals in question. Provided

consent was secured prior to the collection of blood smears however, the study would satisfy condition 2.

The difficult question, in our view, is whether the study satisfies condition 1. Pakistan's National Institute of Malaria Research and Training was involved in the study, suggesting that the study was authorized by an agency of the Pakistani government. However, there is an important question regarding whether any government possesses the legitimate authority to spray insecticide within a person's home without their consent for the purposes of reducing the incidence of malaria. One might argue that such spraying is a legitimate action of government since an individual's failure to spray imposes a risk of infection on others. However, it is interesting to note that the World Health Organization instructs spray operators to secure the consent of householders prior to spraying the interior of their houses (World Health Organization, 2015, p. 69)

Resolving this question requires more analysis than we are in a position to provide here. However, on the assumption that the study does not satisfy condition 1, might it not satisfy conditions 4 and 5 and so not require the consent of participants?

At the time of the study falciparum and vivax malaria were significant health problems in Pakistan and existing evidence showed that the available insecticides – malathion and lambdacyhalothrin – were effective in reducing the incidence of infection (Rowland et al., 2000, p. 472). The study found that alphacypermethrin is as good as or better than these existing insecticides at controlling falciparum malaria, and better than both at controlling vivax malaria. The knowledge gained by the study, considered post-hoc, is therefore very valuable.

Despite this, it's not clear that the study satisfies either condition 4 or 5. First, it may be hard to argue that the non-consensual spraying of the inside of people's houses with insecticide is best characterized as a minor infringement on their property rights. Although the insecticide had been tested for safety and so posed little risk to inhabitants, people have robust rights regarding access to and use of their homes. Nonconsensual indoor spraying, we would suggest, is different from trespassing on private land, the example Gelinas et al. provide of a minor rights infringement. The study may not therefore satisfy condition 4.

Second, although the study could have been reasonably expected to yield valuable knowledge, for it to satisfy condition 5, one would need to argue that the value of this knowledge was sufficient to outweigh the rights infringements involved in the study. Answering this question requires careful empirical and normative judgments, in particular judgments about the potential superiority of the new insecticide over the existing alternatives. In sum, to show that it was permissible for investigators to conduct this study without securing the informed consent of participants, one must discharge significant argumentative burdens.[8]

Conclusion

Governments are increasingly relying on the types of policy experiments described in these cases to evaluate the effectiveness of policy interventions. In this paper, we have sought to contribute to the development of a set of ethical principles to

govern these experiments, specifying the conditions under which investigators must secure participants' informed consent.

Much work remains to be done in this area. While research ethicists have developed a rich and sophisticated literature to address the ethical problems that *clinical* investigators regularly face, social scientist investigators currently lack such a resource. Moreover, because the policy research context is so different from that of the clinical research context, the development of ethical norms and principles to govern the former cannot simply involve the mechanical application of norms and principles developed to govern the latter. Nonetheless, as we hoped to have demonstrated in this paper, the clinical research ethics literature provides a rich resource from which policy research ethicists may draw.

Notes

1. Though scholars are increasingly focusing on the ethics of these types of experiments (Kukla, 2007; Glennerster and Powers, 2013; Teele, 2014; Desposato, 2016; Mackay, 2018).

2. Julius Sim and Angus Dawson defend a similar set of conditions under which cluster-randomized trials are permissible without informed consent (Sim and Dawson, 2012).

Andrew D. McRae et al. arrive at a more restrictive set of conditions under which cluster randomized trials are permissible without informed consent (McRae et al., 2011).

3. Neil C. Manson and Onora O'Neill offer further helpful discussion of the importance of trust in biomedicine and how it may be secured (Manson and O'Neill, 2007, pp. 154-182).

4. Thanks to MG for this phrase.

5. Thanks to JM for raising this objection.

6. We acknowledge that much more needs to be said about which rights infringements are minor and when the social value of certain types of knowledge is sufficient to outweigh such rights infringements. Unfortunately, providing such an account is beyond the scope of our paper.

7. Thanks to an anonymous reviewer for raising this concern and for this example.

8. McRae et al. offer an alternative analysis of this case (McRae et al., 2011).

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