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# Policy Experiments, Informed Consent, and Democratic Authorization

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In a typical clinical trial, researchers are required to obtain participants' informed consent. But for some policy experiments, it is impracticable to obtain informed consent. As a result, these trials sometimes randomize individuals to interventions without their consent. Some critics allege that these experiments fail to show respect for persons and are therefore unethical. Given that governments are increasingly relying on randomized experiments to determine which policies are evidence-based and cost-effective, it is important to assess this criticism. I argue that policy experiments conducted by democratically authorized actors, most notably, democratic governments and their respective institutions, show respect for persons despite not obtaining informed consent.

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### Policy Experiments, Informed Consent, and Democratic Authorization

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Over the past two decades, there has been an explosion in the use of randomized experiments by development economists and other policy researchers operating in lowand-middle-incomes countries (LMICs).<sup>1</sup> Researchers use randomized experiments to study the effects of a wide range of policy interventions pertaining to areas such as poverty, health, and education.<sup>2</sup> Local, regional, and national governments in LMICs increasingly rely on these experiments to implement policies that are evidence-based and cost-effective.<sup>3</sup> Randomized policy experiments are not only conducted in LMICs; these kinds of experiments are increasingly common in high-income countries (HICs) too.<sup>4</sup>

In a typical randomized clinical trial, researchers are required to obtain participants' informed consent. But for some (not all) policy experiments, obtaining consent from those targeted by an intervention may compromise the scientific validity of a study in various ways. Randomization helps reduce selection bias, but selection bias can still be an issue during the recruitment stage of a policy experiment. One solution is to require individuals to enroll in a trial, such as in a recent basic income experiment run by the Finnish government where participation in the treatment arm was mandatory for 2,000 randomly selected persons already receiving unemployment benefits.<sup>5</sup>

Contamination bias is another major source of concern. Contamination bias occurs when individuals in different trial arms interact in ways that affect the outcomes being measured. The possibility of these "leaks" can cast doubts on the scientific validity of a

- <sup>3</sup> Randomized experiments do have limitations when it comes to guiding policy. See Cartwright and Hardie (2012) for extensive discussion.
- <sup>4</sup> In fact, the first wave of enthusiasm for randomized policy experiments took place in the US during the 1970s and 1980s. See Gueron and Rolston (2013) for a historical overview.
- <sup>5</sup> Kangas 2019. Thanks to the editor of *Political Philosophy* for suggesting this example.

<sup>&</sup>lt;sup>1</sup> Banerjee, Duflo, and Kremer 2019.

<sup>&</sup>lt;sup>2</sup> See Banerjee and Duflo (2011) and Karlan and Appel (2011) for general introductions and Glennerster and Takavarsha (2013) for a comprehensive overview of how randomized policy evaluations are conducted. For wide-ranging discussions of the merits and demerits of randomized policy experiments, see anthologies such as: Cohen and Easterly 2009; Teele 2014; Ogden 2017; and Bédécarrats, Florent, and Roubaud 2020.

study. Contamination bias is often addressed using a cluster randomized experimental design.<sup>6</sup> In a cluster randomized trial (CRT), the unit of randomization is a social entity rather than an individual, which can result in random assignment of an intervention to a whole group (i.e., a cluster) of non-consenting individuals. An influential study on the effects of cost-sharing on insecticide-treated bed net (ITN) usage in Kenya is an illustrative example.<sup>7</sup> By randomizing health clinics in different villages rather than individuals, researchers ensured that ITNs were either freely distributed or sold at the same subsidized price to all pregnant women within a community. This lessened the possibility that pregnant women in one group (e.g., the cost-sharing group) would be influenced by or observe the behavior of pregnant women in another group (e.g., the free-distribution group), and which further allowed the researchers to assess the community-level effects of increased ITN usage.

While scientific validity is an important consideration, it is also worth emphasizing that many pressing policy questions can only be studied experimentally using a CRT. Consider a study that evaluates the effects of school closures on the transmission of respiratory viruses (such as COVID-19) and educational outcomes, such as the proposed and rejected (on consent grounds) School Opening in the Age of Pandemic (SOAP) study in Norway.<sup>8</sup> To conduct such an experiment, researchers would have randomly assigned entire municipalities to a school opening arm and other municipalities to a school closure arm. While the families of children residing in municipalities assigned to the school opening arm of the trial could opt for homeschooling if they wish to remain cautious, it would be infeasible to relocate families in the school closure arm to municipalities in the school opening arm. For many policy questions of interest, it is not possible to design an experiment in a way that allows for a treatment to be administered in an individuated manner.

It is perhaps unsurprising that the lack of consent in policy experiments has come under ethical scrutiny. Informed consent is, after all, the most known and well-regarded requirement of ethical clinical research.<sup>9</sup> Though there are methodological and practical

<sup>&</sup>lt;sup>6</sup> See Dron et al. (2021) for an overview.

<sup>&</sup>lt;sup>7</sup> Cohen and Dupas 2010.

<sup>&</sup>lt;sup>8</sup> See Fretheim et al. (2020) for a copy of the rejected protocol and Fretheim et al. 2024 for additional discussion.

<sup>&</sup>lt;sup>9</sup> The first principle in the Nuremberg Code famously states that "the voluntary consent of the human subject is absolutely essential" (Nuremburg Military Tribunal 1996). Other statements of research ethics that emphasize the importance of informed consent include The Declaration of Helsinki (World Medical Association 2025), The Council for International Organizations of Medical Ethics' (CIOMS) International Ethical Guidelines for Health-related Research Involving Humans (CIOMS 2016, Guideline 9), and the Belmont Report (National Commission 1979).

reasons to not seek informed consent in policy experiments, many are inclined to think these considerations should not override informed consent requirements. Christopher Barrett and Michael Carter write that the lack of consent in policy experiments "raises the subtle but important distinction between treating human beings as willful agents who have a right to participate or not as they so choose, versus treating them as subjects to be manipulated for research purposes."<sup>10</sup> Nimi Hoffmann makes her position more explicit when she writes that the lack of consent in policy experiments "violates the personhood of some of the world's most vulnerable people – impoverished black and brown people, many of whom are women."<sup>11</sup>

As I argue in this article, criticisms such as those above are misguided because informed consent is not an absolute deontic constraint on research involving human subjects.<sup>12</sup> My position stems from following Alan Wertheimer in understanding informed consent as an *ethical mechanism* that promotes two distinct ethical values: (A) autonomy and (B) welfare.<sup>13</sup> These values correspond to two important ethical objectives in human subjects research: (a) protecting individuals' autonomy rights and (b) protecting and promoting individuals' welfare interests. Both (a) and (b) are constitutive elements of a foundational principle of research ethics: *respect for persons*.<sup>14</sup>

The main position I argue for in this article is that policy experimentation without consent shows respect for persons when it is *democratically authorized*.<sup>15</sup> To be clear, democratic authorization does not require that everyone targeted or affected by a policy experiment gets to vote on whether the experiment goes ahead. Of course, if this direct democratic approach were both feasible and desirable, it would be sufficient for democratic authorization.<sup>16</sup> But in most cases democratic authorization involves

<sup>13</sup> Wertheimer 2010, ch. 3. See also Miller and Wertheimer 2010; 2011.

<sup>15</sup> This position complements the more general account of the democratic virtues of relying on randomized experiments for policymaking found in Tanascosa and Leigh (2024).

<sup>&</sup>lt;sup>10</sup> Barrett and Carter 2010, p. 520.

<sup>&</sup>lt;sup>11</sup> Hoffmann 2020, p. 2. Hoffmann calls for a moratorium on policy experiments in LMICs on these grounds.

<sup>&</sup>lt;sup>12</sup> This should not come as a surprise to anyone familiar with US federal regulations governing human subjects research, which provide exemptions to informed consent requirements. See 45 CFR 46.116(e)–(f) (US Department of Health and Human Services 2025). See also CIOMS 2016, Guideline 10.

<sup>&</sup>lt;sup>14</sup> See Millum and Bromwich (2024) for further analysis of the requirement that human subjects research show respect for persons. An important way my account differs from theirs is that showing respect for persons involves accounting for individuals' welfare interests in addition to protecting their autonomy rights.

<sup>&</sup>lt;sup>16</sup> With respect to desirability, see Achen and Bartels (2016, ch. 3).

an elected legislative body delegating its powers to a government institution in the executive branch—typically an administrative agency or a ministry. The government institution will then, at its discretion, conduct or authorize a policy experiment in carrying out its mandate. However, this does not rule out the possibility of a democratic legislature directly authorizing an experiment, as was the case in the Tennessee Student Achievement/Teach Achievement Ratio (STAR) study on the effects of classroom size on educational outcomes.<sup>17</sup> This policy experiment was directly authorized (and funded) by the Tennessee state legislature. Whether legislative authorization is preferable to administrative discretion (combined with legislative oversight) is ultimately an issue that I cannot settle here.<sup>18</sup>

After some clarificatory remarks in Section I, the rest of this article is structured around the following argument: (P1) If an ethical mechanism achieves objectives (a) and (b), then it shows respect for persons; (P2) Democratic authorization is an ethical mechanism that achieves objectives (a) and (b); (C) Therefore, democratic authorization shows respect for persons. To support this argument, I draw on both bioethics and democratic theory. When put into dialogue together, bioethics and democratic theory show that policy experimentation without consent can show respect for persons not just in the abstract, but also in the less-than-ideal circumstances that characterize both LMICs and HICs. In Section II, I motivate P1 by analyzing the concept of informed consent within the context of clinical research. In Section III, I review recent contributions to the issue of research without consent to motivate P2. In Sections IV and V, I support each conjunct of P2 (respectively) by drawing on instrumental justifications of democracy.<sup>19</sup> I conclude in Section VI by flagging some important empirical considerations relevant to the ethics of non-consensual policy experiments.

#### I. CLARIFYING THE ISSUE

As noted at the outset, an ethical challenge with policy experiments is that they often make obtaining consent impracticable. Before proceeding, it is important to make two clarificatory points. The first is that there are multiple ways a policy experiment can

<sup>&</sup>lt;sup>17</sup> Word et al. 1990.

<sup>&</sup>lt;sup>18</sup> See Heath (2020, ch. 6) for a sustained defense of administrative discretion that is relevant to policy experiments.

<sup>&</sup>lt;sup>19</sup> Instrumental justifications of democracy appeal to the good consequences associated with using democratic procedures. Intrinsic (or non-instrumental) justifications appeal to the ethical values inherent in democratic procedures (Christiano and Bajaj 2024). Intrinsic justifications are important but do not play a role in my main argument.

wrong individuals that has nothing to do with a lack of informed consent.<sup>20</sup> For example, governments have a duty to treat the interests of their citizens with equal concern.<sup>21</sup> A government may violate this duty if it provides some individuals with a promising policy intervention but subjects others to an inferior status quo policy as part of an experiment. This scenario raises the question of how randomization can be fair in a policy experiment, which should be kept separate from the issue of research without consent.<sup>22</sup> Consider how, unlike informed consent, scientific validity is a necessary but insufficient aspect of what make clinical research ethical.<sup>23</sup> Scientific validity is necessary because, for research to be socially valuable, it needs to be conducted in a methodologically rigorous manner. But of course, there are multiple ways that scientifically valid clinical research can be unethical. Similarly, there are also multiple ways that a policy experiment can be unethical. My focus here is only the issue of whether policy experimentation without consent can show respect for persons, which I maintain is a necessary but insufficient aspect of what makes human subjects research ethical.

The second clarificatory point is that not all policy experiments involve a complete lack of consent. Consider once again the typical clinical trial. After being randomly assigned to treatment and control groups, individuals consent to an individuated intervention, e.g., an experimental drug. To assess whether the experimental drug works, researchers also obtain consent to gather data by drawing blood samples, taking biopsies, or looking at medical records. So, in a typical clinical trial, individuals consent to (at least) two different things: (i) receiving a randomly determined intervention and (ii) observation and data collection.

Policy experiments in which individuals consent to (i) and (ii) need not concern us here. Policy experiments in which individuals neither consent to (i) nor (ii) are clearly of interest, but so are experiments in which individuals can consent to (ii). Consider the study on cost-sharing and ITN usage discussed at the outset. Pregnant woman who purchased ITNs and who took part in the study consented to tracking and to having their hemoglobin levels recorded for data collection purposes. One may be inclined to think that policy experiments are ethically innocuous when individuals can consent to data collection, such as in the example above. The study on ITN usage illustrates the general problem some see with the lack of consent in policy experiments: none of the pregnant Kenyan women consented to having the price of ITNs randomized for

<sup>&</sup>lt;sup>20</sup> See MacKay (2024) for an overview.

<sup>&</sup>lt;sup>21</sup> Christiano 2008.

<sup>&</sup>lt;sup>22</sup> See MacKay (2020) for extensive analysis of when randomization is fair in a policy experiment and Picchio (2025) for extensions to experiments in development economics.

<sup>&</sup>lt;sup>23</sup> Emanuel, Wendler, and Grady 2000.

research purposes.<sup>24</sup> In other words, these women had their environments deliberately manipulated (without their having any say in the matter) to generate policy-relevant knowledge for the benefit of others.

What I suggest is the salient ethical problem with the lack of consent in policy experiments is that individuals do not consent to (i) receiving a randomly determined intervention. Though it is possible to obtain consent for data collection in some policy experiments, I will only briefly comment on what kinds of data collection require informed consent as my main argument applies *mutatis mutandis* to data collection without consent. Much of the discussion going forward focuses on when researchers may permissibly intervene without obtaining the consent of individuals targeted by an intervention. This, I take, is the salient ethical issue with the lack of consent in policy experiments.

#### **II. INFORMED CONSENT**

In this section, I analyze the concept of informed consent within the context of clinical research. This is done to motivate the idea that (P1) if an ethical mechanism (a) protects individuals' autonomy rights and (b) protects and promotes individuals' welfare interests, then it shows respect for persons.

#### A. What's the Point of Informed Consent?

A full theory of informed consent is well beyond the scope of this article.<sup>25</sup> But like other commentators, I maintain that the most basic function of consent is that it permits others to interact with us in ways that would otherwise be wrong. Though a full theory of consent is not possible here, it is still important to say more about the two values that informed consent promotes because these values correspond to two important ethical objectives in human subjects research: (a) protecting individuals' autonomy rights and (b) protecting and promoting individuals' welfare interests. As mentioned at the outset, both (a) and (b) are constitutive elements of a more fundamental principle in research ethics: *respect for persons*. In my framing, informed consent is an *ethical mechanism* for achieving (a) and (b). And as I argue further on, democratic authorization is another ethical mechanism that achieves (a) and (b).

<sup>&</sup>lt;sup>24</sup> Perhaps these women tacitly consented to partake in research when they agreed to purchase an ITN. Evaluating this response requires, among other things, determining whether the pregnant women's purchase was sufficiently voluntary, which requires determining whether researchers withheld resources these women were entitled to in the first place. See Picchio (2024) for further discussion of this issue.

<sup>&</sup>lt;sup>25</sup> See Faden and Beauchamp 1986. Cf. Miller and Wertheimer 2010; 2011.

#### **B.** Autonomy

Start with (a) the protection of individuals' autonomy rights. Autonomy, as I understand it for present purposes, is comprised of two elements. In order of importance, these elements are: (i) personal sovereignty and (ii) self-authorship. Personal sovereignty is the idea that there is a sphere of control over which persons are rightful rulers, viz., individuals have "final say" over what happens within this sphere. Joel Feinberg's analogy with a sovereign state is helpful: "The politically independent state is said to be sovereign over its territory. Personal autonomy similarly involves the idea of having a domain or territory in which the self is sovereign."26 Understood this way, our autonomy rights are violated when there is illegitimate interference within our "jurisdiction" or rightful sphere of control. However, our legitimate sphere of control not only limits the actions of others, but also grants us a sphere of permissible action. Within our sphere of permissible action is a range of choices over what kind of life to lead. This is the notion of autonomy understood as self-authorship. Joseph Raz captures the spirit of autonomy as self-authorship as follows: "The autonomous person is a (part) author of his life. The ideal of personal autonomy is the vision of people controlling, to some degree, their own destiny, fashioning it through successive decisions about their lives."27

Both personal sovereignty and self-authorship are reflected in how bioethicists understand autonomy. In their influential *Principles of Biomedical Ethics*, Tom Beauchamp and James Childress write: "The autonomous individual acts freely in accordance with a self-chosen plan, analogous to the way an independent government manages its territories and establishes its policies."<sup>28</sup> We can then further say that a person's autonomy rights are violated when they are not granted adequate control over the direction their life takes.<sup>29</sup>

One of informed consent's functions is that it (a) protects individuals' autonomy rights. But we also saw above that autonomy is composed of (at least) two elements: (i) personal sovereignty and (ii) self-authorship. This suggests that there are two corresponding types of autonomy rights that it is important to distinguish between.

<sup>&</sup>lt;sup>26</sup> Feinberg 1986, p. 52.

<sup>&</sup>lt;sup>27</sup> Raz 1986, p. 369.

<sup>&</sup>lt;sup>28</sup> Beauchamp and Childress 2019, p. 101.

<sup>&</sup>lt;sup>29</sup> To genuinely be authors of our own lives, our choices must also reflect our deepest commitments. This suggests a third element of autonomy: nonalienation. The unwilling addict does not genuinely author his life because his choices do not reflect his second-order desire to not use drugs (Frankfurt 1971). Persons whose attitude-forming processes are distorted by unjust social factors (or simply brainwashed) may also not be genuine self-authors. See Enoch (2020) for discussion of this problem in relation to consent.

As I understand them, the autonomy rights corresponding to personal sovereignty are claims to non-interference or *negative rights*. These negative rights are possessed by all humans, exist pre-institutionally, and serve as a constraint on the actions of both individuals and governments.<sup>30</sup> One of the most important negative rights is the right to bodily integrity. In clinical contexts, it is typically the right to bodily integrity that accounts for the "consent" aspect of informed consent requirements. Because persons are sovereign over their bodies, clinicians and researchers must obtain permission to introduce or collect a substance into or from someone's body in a way that is reminiscent of how governments regulate what enters or leaves its territories.

Not all autonomy rights correspond to personal sovereignty. What I refer to as *entitlements* correspond to autonomy understood as self-authorship. By entitlements, what I have in mind are claims to assistance that allow persons to meaningfully pursue a self-authored life plan. Because they are claims to assistance, entitlements are *positive rights*. Entitlements provide the basis for the "informed" part of informed consent requirements. In clinical research contexts, potential research participants are entitled to the information they need to ensure enrollment is congruent with their values and life plan. Researchers, in turn, have a correlative obligation to disclose such information to avoid illegitimate control over someone's decision–making.<sup>31</sup>

#### C. Welfare

Autonomy as self-authorship is not the sole basis for an entitlement to information. Informed consent also (b) protects and promotes individuals' welfare interests, and it is important to stress that (a) and (b) are distinct objectives corresponding to distinct values. After all, an individual's autonomous choice may involve consenting to an interaction they know makes them worse-off.<sup>32</sup> However, these two objectives often coincide. There are circumstances in which an individual's autonomous choices best promotes their welfare. When reasoning adequately and sufficiently informed, individuals are in the unique epistemic position of knowing what is likely to promote their welfare interests.<sup>33</sup> And this further means that individuals are often in the unique

<sup>&</sup>lt;sup>30</sup> One can think of these rights as *natural rights* as they hearken back to the philosophical tradition associated with Locke's *Second Treatise of Government* (Locke 1980).

<sup>&</sup>lt;sup>31</sup> Bromwich and Millum 2015.

<sup>&</sup>lt;sup>32</sup> While this is a well-accepted conceptual possibility, the prevailing ethical and regulatory framework for human subjects research makes this possibility unlikely. Institutional Review Boards (IRBs) often prevent individuals from ever having the option of consenting to harmful or high-risk clinical interventions. See Wertheimer (2010, ch. 2) for further discussion.

<sup>&</sup>lt;sup>33</sup> See Mill's On Liberty for the canonical defense of this claim (Mill 1998).

epistemic position of knowing what risks to accept (or refuse) to (b) protect and promote their welfare interests. Note that in making this point, I take no position on the issue of what the ultimate constituents of well-being are. I only adopt an *evidentialist* view of the relation between informed choice and welfare.<sup>34</sup> What this means is that, when one is acting on self-regarding preferences, reasoning adequately, and sufficiently informed, this provides strong evidence that one's consensual choice protects and promotes their welfare.

#### D. Minimalism and the Understanding Requirement

Despite the centrality of informed consent in the prevailing ethical and regulatory framework for human subjects research, it is no secret that the consent mechanism can fail to promote (A) autonomy and (B) welfare if our benchmark is some combination of an "unencumbered self"<sup>35</sup> and a utility maximizer. We know from fifty years of research in behavioral economics that cognitive constraints (sometimes) lead humans to make autonomous choices that deviate from rational norms.<sup>36</sup> Bioethicists have similarly taken note of these constraints. There is now an abundance of empirical evidence documenting the various ways research participants fail to fully understand their participation in research.<sup>37</sup> Even if researchers go to great lengths to disclose all the relevant information that a decision maker *ought* to be provided with to make an informed decision, there is bound to be a discrepancy between what information is disclosed and what is actually understood by consenting research participants. Yet if we accept there is often misconception about what involvement in clinical research entails, and we accept a view of informed consent on which the contents of what is understood must be identical to the contents of what is disclosed (the "standard view"), we arrive at the startling (and implausible) conclusion that most clinical research should come to a halt.<sup>38</sup> At the same time, no one is calling for a moratorium on clinical research.

The tension highlighted above has prompted philosophers and bioethicists to think more carefully about the understanding requirement for valid consent. Careful analysis of the problem has led Joseph Millum and Danielle Bromwich to defend *minimalism* with

<sup>&</sup>lt;sup>34</sup> Hausman 2011, ch. 7.

<sup>&</sup>lt;sup>35</sup> Sandel 1982.

<sup>&</sup>lt;sup>36</sup> Kahneman 2011.

<sup>&</sup>lt;sup>37</sup> See Flory, Wendler, and Emanuel (2008) for an overview.

<sup>&</sup>lt;sup>38</sup> Sreenivasan 2003.

respect to understanding.<sup>39</sup> On their account, a research participant must understand three things to give valid consent: (1) that she is giving consent; (2) how to exercise her right to give or refuse consent; and (3) to what she is being asked to consent. The exact details of Millum and Bromwich's proposal and whether it is ultimately the correct minimalist account need not concern us here.<sup>40</sup> What is important to emphasize is that minimalism about informed consent can shed light on the ethics of real-world policy experiments. As we proceed, it will be important to not let an idealized understanding of informed consent set an unrealistic benchmark for democratic authorization. In the same way that perfect rationality is not required for valid consent to a clinical trial, I will suggest that a perfectly democratic society is not required for valid authorization to a policy experiment.

#### **III. RESEARCH WITHOUT INFORMED CONSENT**

In this section, I review recent contributions to the issue of research without consent to motivate P2 of my main argument. I then defend P2 in Sections IV and V.

#### A. Healthcare Research Without Informed Consent

Lukas Gelinas, Alan Wertheimer, and Franklin Miller have developed a framework for assessing when and why research without consent is permissible.<sup>41</sup> Though Gelinas et al.'s focus is the healthcare context, their approach extends to policy evaluation. Drawing on an analysis of informed consent like the one above, Gelinas et al. propose two conditions that are jointly sufficient for making research without consent permissible: (1) the research stands to infringe on no right of the participants and (2) it is impracticable to obtain consent.<sup>42</sup> Before elaborating on (1) the individual rights condition, it is important to say something about (2) the impracticability condition. Gelinas et al. emphasize that it is still important to obtain consent in cases where it is practicable *even if* failure to do so violates no one's rights. This is because doing so promotes public trust and transparency in the research enterprise. While this is an important consideration, what promotes public trust in the research enterprise is an empirical matter and cannot be settled by philosophical analysis. To avoid speculation, I set this consideration aside for now but return to it in my concluding remarks.

<sup>&</sup>lt;sup>39</sup> Millum and Bromwich 2018; 2021.

<sup>&</sup>lt;sup>40</sup> Cf. Sreenivasan 2021.

<sup>&</sup>lt;sup>41</sup> Gelinas, Wertheimer, and Miller 2016.

<sup>&</sup>lt;sup>42</sup> Ibid., p. 35. Gelinas et al. propose a second criterion for when research without consent is permissible, but I only focus on the first.

What is important to focus on is Gelinas et al.'s (1) individual rights condition. Take Gelinas et al.'s analysis of quality improvement (QI) studies undertaken at the institutional level. An institutional level QI study will evaluate the effectiveness of an intervention on healthcare delivery or patient outcomes in a healthcare facility or healthcare system. QI studies are regularly done without any informed consent.<sup>43</sup> Gelinas et al. argue that, because institutions such as hospitals and healthcare systems possess rights of control, QI studies without consent are permissible when they evaluate interventions within their legitimate sphere of control. Like Gelinas et al., I will not specify the exact boundaries of where a healthcare institution's rights of control end and where a patient's right to exercise their autonomy rights over their healthcare decisions begin. Denying that hospitals and healthcare systems have a legitimate sphere of control would be highly implausible, as evidenced by the example below, and which also illustrates Gelinas et al.'s approach to research without consent:

institutions have a right to require that clinicians wash their hands with a particular type of disinfectant soap, without consulting or obtaining consent from patients for this practice. Given that this is a practice within the decisional authority of the institution, so long as the institution ensures a standard level of care with regard to hand washing and sanitation, institutions should have the right to conduct research comparing two types of disinfectant soap for use by clinicians without patient consent. The rights of patients will not be infringed by the conduct of such QI research without consent.<sup>44</sup>

With respect to research without consent, the main insight to extract from the passage above is the following principle:

*Intervention without Consent:* If *X* possesses the right to implement intervention *I* in population *P* in a non-research context, then *X* does not violate any constituent of *P*'s autonomy rights by implementing *I* without consent in a research context.

<sup>44</sup> Gelinas, Wertheimer, and Miller 2016, p. 37.

<sup>&</sup>lt;sup>43</sup> There is some controversy over whether QI studies count as "research" as defined by US federal regulations. US federal regulations state that research "means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." See 45 CFR 46 102(l) (US Department of Health and Human Services 2025). If QI studies do not count as research in this sense, then they are exempt from informed consent requirements. This is how QI studies have been traditionally allowed to proceed without informed consent.

In the example above, the healthcare facility (presumably) has the right to decide which disinfectant soap a clinician uses in its hospitals. Therefore, the QI study on disinfectant soap is permissible from an autonomy-based perspective. The autonomy rights of clinicians and hospital patients are not violated since they lack a right to determine which disinfectant soap a hospital uses. The disinfectant soap a hospital uses is not within the legitimate sphere of control possessed by these individuals.

Contrast the QI study with a typical clinical trial. The kinds of interventions and data collection procedures involved in a clinical trial require bodily interventions. Clinical researchers cannot just force a promising experimental drug down the throats of research participants, nor can they perform a nonconsensual lumbar puncture while a research participant is unconscious. These kinds of bodily intrusions are forbidden because people have a right to bodily integrity. This entails researchers also have a correlative duty to respect such a right, hence why informed consent is so important in the context of clinical research.

#### **B.** Policy Experimentation Without Informed Consent

Douglas Mackay and Averi Chakrabarti have extended Gelinas et al.'s framework to government policy experiments.<sup>45</sup> The key insight to MacKay and Chakrabarti's analysis of policy experimentation without consent is that *governments* are also institutions with rights of control. Specifically, government institutions have rights of control over *policy* decisions within a given territory. As these commentors put it: "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."<sup>46</sup> Using this insight, MacKay and Chakrabarti propose two jointly sufficient conditions for permissible policy experimentation without consent: (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 involve the violation of participants' autonomy rights.<sup>47</sup>

<sup>&</sup>lt;sup>45</sup> MacKay and Chakrabarti 2019.

<sup>&</sup>lt;sup>46</sup> Ibid. p. 192.

<sup>&</sup>lt;sup>47</sup> Ibid., p. 188. Notably, MacKay and Chakrabarti dispense with Gelinas et al.'s impracticability condition when policy research is conducted in *ideal* conditions. These commentators plausibly suggest that in ideal conditions, the impracticability condition is redundant since ideal conditions are those in which researchers comply with practices and principles designed to protect individuals' rights and interests, and this is publicly known to all. However, MacKay and Chakrabarti do argue that the impracticability condition is important in non-ideal

The analysis of informed consent provided earlier helps fill in the details of the second condition in MacKay and Chakrabarti's framework. Because persons possess a right to bodily integrity, any policy research involving bodily intrusions (such as blood draws) clearly requires consent regardless of institutional context. Other data collection procedures that interfere with an individual's personal sovereignty (e.g., their privacy rights) are similarly forbidden.

Matters are less straightforward with respect to MacKay and Chakrabarti's first condition (the right to rule condition). MacKay and Chakrabarti are certainly appealing to *Intervention without Consent* combined with the notion of a government's "right to rule" to justify this first condition. However, MacKay and Chakrabarti never explain where a government institution's right to rule over policy comes from. This is an issue fundamentally connected to whether a government has political legitimacy, i.e., whether it is morally justified in wielding political power.<sup>48</sup> MacKay and Chakrabarti do suggest that, unless one is a philosophical anarchist<sup>49</sup> or holds a theory of political legitimacy that no real-world governments currently meet,<sup>50</sup> one can maintain that there is a wide range of policy interventions that democratic governments (and their various institutions) have a right to implement. Though I do not disagree, a more complete account of the ethics of policy experiments requires further engagement with democratic theory for reasons I expand on below.

#### C. Three Difficulties with the Right to Rule Condition

There are three difficulties with MacKay and Chakrabarti's right to rule condition (as initially presented) that are in tension with informed consent's two objectives, and which can ultimately be remedied with insights from democratic theory. The first difficulty is that even though autonomy as personal sovereignty is accounted for in condition (2), something should be said about the background conditions (i.e., the institutional framework that governs a society) that ensure such rights violations do not occur in a frequent and systematic fashion. This not only applies to the data collection stage of a policy experiment but the intervention stage as well. The issue of favorable background conditions is often taken for granted in discussions of clinical

circumstances (Ibid., pp. 195–196). This consideration is, of course, highly relevant. And though I am sympathetic to this consideration, whether the impracticability condition does, in fact, promote public trust in real-world circumstances is ultimately an empirical matter, which I largely set aside here.

<sup>&</sup>lt;sup>48</sup> Buchanan 2002.

<sup>&</sup>lt;sup>49</sup> E.g., Wolff 1970.

<sup>&</sup>lt;sup>50</sup> E.g., Simmons 1979.

research ethics, but it should certainly not be taken for granted when analyzing policy experiments—especially policy experiments in LMICs.

The second difficulty concerns autonomy understood as self-authorship. There is an unexplored tension between a government's right to rule and its residents' autonomy rights in condition (1) of MacKay and Chakrabarti's framework. Governments (and other social institutions) have a profound impact in shaping the course of its citizens' lives. An important way that governments affect their citizens' lives is through its policy decisions. This suggests that policy experiments have the potential to undermine autonomy understood as self-authorship. Policy experiments involve manipulating some aspect of an individual's environment for the sake of generating policy relevant knowledge. More specifically, they can involve manipulation of an individual's entitlements to socioeconomic resources and opportunities. This connection between autonomy as self-authorship and access to resources and opportunities should not be downplayed. After all, one of John Rawls' most influential insights is that these entitlements bear on an individual's ability to pursue a meaningful life plan.<sup>51</sup> Poverty is not only bad because of its effects on human welfare, but also because it deprives individuals of the ability to make meaningful choices about their lives.<sup>52</sup> Similarly, one's access to healthcare resources (such as ITNs) can affect whether one is healthy enough to partake in the social, political, and economic activities of their society.<sup>53</sup> And the duration and quality of one's education is important not just because of the economic returns, but also because it enables one to develop the knowledge, skills, and critical thinking abilities necessary to make informed decisions in life.54

The third difficulty concerns human welfare. Like with much research involving human subjects, policy experiments come with risks of causing (non-trivial) harm to individuals. In addition to protecting autonomy rights, informed consent also shows respect for persons by only exposing research participants to (substantial) risks to their well-being that they are willing to accept. After all, sacrificing the (substantive) welfare interests of an individual (or minority of individuals) to promote a socially valuable end (e.g., scientific research) is the paradigm example of ignoring the "separateness of persons"<sup>55</sup> and thereby failing to show respect. Since it is impracticable to obtain consent in some policy experiments, there is the troubling possibility of doing just this. And even in cases of policy experiments where it is possible to obtain consent for

<sup>&</sup>lt;sup>51</sup> Rawls 1971.

<sup>&</sup>lt;sup>52</sup> Sen 1999.

<sup>&</sup>lt;sup>53</sup> Daniels 1985.

<sup>&</sup>lt;sup>54</sup> Brighouse 2006.

<sup>&</sup>lt;sup>55</sup> Rawls 1971, p. 27.

intervention and data collection (and their associated risks), there is still the troubling possibility of imposing risks on (non-consenting) bystanders. This consideration is especially salient in LMICs, where there is a tendency for socioeconomic interventions to have unintended effects.<sup>56</sup>

#### D. The Need for Democratic Theory

The first two conditions of MacKay and Chakrabarti's framework for policy experimentation without consent are worth maintaining. However, their framework requires further elaboration to address the three difficulties above. To address these worries, I argue that a clarificatory—but nevertheless important—third condition is needed: (3) a government institution possesses a right to rule over a sphere of policy *if the institution is authorized to do so by a democratic procedure.* With this addition, MacKay and Chakrabarti's framework would comply with the requirement that human subjects research shows respect for persons. This is because, as I argue below, (P2) democratic authorization is like informed consent in that it is an ethical mechanism that (a) protects individuals' autonomy rights and (b) protects and promotes individuals' welfare interests.

Though I argue below that democratic authorization is the source of a government institution's right to rule over a sphere of policy, it is important to make clear that there are policy interventions that not even democratically authorized actors can experiment with because they violate an individual's autonomy rights. Consider, for example, a (completely hypothetical) policy experiment that evaluates the effects of limiting free speech on educational outcomes. Unlike the proposed SOAP or Tennessee STAR experiments discussed at the outset, no democratic government could permissibly conduct or authorize such a policy experiment. The intervention of interest conflicts with an individual's right to freedom of expression, and as such, would not be within the legitimate sphere of control that even democratic governments possess. I maintain throughout that democratic governments cannot conduct or authorize non-consensual policy experiments that involve interventions (or data collection procedures) that conflict with individuals' autonomy rights. However, for reasons I expand on below, this is an unlikely to happen due to the close connection between democracy and autonomy.

#### IV. DEMOCRACY AND AUTONOMY

In this section, I defend the first conjunct of P2 by arguing that democratic authorization is an ethical mechanism that (a) protects individuals' autonomy rights.

<sup>&</sup>lt;sup>56</sup> Acemoglu 2010.

Implicit in the common understanding of democracy is the idea that democracy is a system of governance that respects individual freedom. This idea can be cashed out in (at least) two ways (a second way is discussed and rejected in Section IV.B). The first way appeals to an empirical regularity between the protection of personal sovereignty and democratic institutions. This empirical regularity licenses itself to social scientific investigation. There is strong empirical evidence suggesting that democracies do a better job of protecting a special class of negative rights than non-democracies.<sup>57</sup> These negative rights are often referred to as *personal integrity rights*. Personal integrity rights discussed in this context include the right to not to be tortured, the right to not be arbitrarily imprisoned, and the right to not be murdered or disappeared by the state. These personal integrity rights presumably stem from a more fundamental right to bodily integrity, which I suggested provides part of the ethical basis for a right to not be medically experimented on without consent.

The link between democracy and the protection of personal sovereignty is an important first step in showing that democratic authorization is an ethical mechanism that (a) protects individuals' autonomy rights. The fact that a policy experiment is conducted in a democratic society provides strong evidence that background conditions are such that they do not enable fundamental rights violations by public or private actors conducting human subjects research (including policy experiments). Specifically, the link between democracy and personal sovereignty kicks in when a society that meets the conditions for what Thomas Christiano calls *minimally egalitarian democracy*. The conditions are:

- 1. Persons have formally equal votes that are effective in the aggregate in determining who is in power, the normal result of which is a high level of participation of the populace in the electoral process.
- 2. Persons have equal opportunities to run for office, to determine the agenda of decision making, and to influence the processes of deliberation. Individuals are free to organize political parties and interest group associations without legal impediment or fear of serious violence, and they are free to abandon their previous political associations. They have freedom of expression at least regarding political

<sup>&</sup>lt;sup>57</sup> See Christiano (2011) for a philosophically oriented review of the empirical literature. See Davenport (2007) for more extensive discussion and empirical analysis. An important qualification that Davenport analyzes (and which cannot be addressed here) is that the influence of democracy on personal sovereignty can be counteracted in countries with a recent history of political conflict.

matters. In such a society, there is normally robust competition among parties and a variety of political parties that have significant presence in the legislature.

3. Such a society also acts in accordance with the rule of law and supports an independent judiciary that acts as a check on executive power.<sup>58</sup>

As Christiano makes clear, a minimally egalitarian democracy "need not by any means be fully just nor need it fully live up to the ideals of democracy."<sup>59</sup> For example, a minimally egalitarian democracy is consistent with wealth inequalities limiting opportunities for *substantive* (rather than *formal*) equal influence over political decision making. A minimally egalitarian society may also not guarantee the full range of rights associated with the ideal of personal sovereignty if these rights are not connected to the democratic process. But to qualify as a minimally egalitarian democracy, it is crucial that racial and ethnic minorities should have "the protections of the rule of law, free association, and free expression, as well as equal opportunities for organizing politically effective groups."<sup>60</sup>

The conditions for minimally egalitarian democracy are worth highlighting because they provide a realistic standard for whether a government is justified in wielding political power. Going forward, I maintain that a real-world government is legitimate if the society it rules over meets the conditions for minimally egalitarian democracy. This further implies that a government institution possesses a right to rule over a sphere of policy if it is authorized to do so by a legitimate government, i.e., a government that rules over a minimally egalitarian democracy.

Despite the above, the link between minimally egalitarian democracy and personal sovereignty can only carry the argument so far. As specified earlier, autonomy is comprised of another element, i.e., self-authorship. My defense of P2's first conjunct is incomplete without some discussion of democracy and autonomy as self-authorship.

#### **B. Democracy and Self-Authorship**

Though it is hard to deny that personal integrity rights are of the utmost importance, personal sovereignty cannot fully account for democracy's importance. If it could, then then there would be nothing objectionable with a society ruled by a benevolent autocrat. After all, there is nothing incoherent or contradictory about an autocrat who goes to great lengths to protect the personal sovereignty of his subjects. But in such a

<sup>&</sup>lt;sup>58</sup> Christiano 2011, p. 146.

<sup>&</sup>lt;sup>59</sup> Ibid., p. 146.

<sup>&</sup>lt;sup>60</sup> Ibid., p. 146.

society, the autocrat's subjects would have no control over political decision making, which has a profound influence on the course of anyone's life. Many are inclined to think that there is something regrettable about institutional arrangements that do not grant individuals some control over the influence of politics on their lives. But unfortunately, the intuition many share about democracy and autonomy as self-authorship is hard to make sense of. There are well known complications with the view that democracy promotes individuals' autonomy by making them part of authors of law and policy, the most notable being the possibility of being on the losing side of a vote.<sup>61</sup> One can still make the case for democratic arrangements facilitating *joint* authorship of law and policy and thereby promoting a form of *collective autonomy* distinct from individual autonomy.<sup>62</sup> But in the case of minimally egalitarian democracies (i.e., real-world democracies), it is pretty clear that the decisions of both elected and unelected government officials do not typically reflect the will of the people, so citizens are often subject to laws and policies that they did not jointly author in any meaningful sense.<sup>63</sup>

None of this should be taken to suggest that democratic authorization conflicts with autonomy as self-authorship. The value of autonomy as self-authorship should not be confused with *complete* control over the direction one's life takes. Complete control is an untenable standard as there are aspects of any person's life that they may deem important but are beyond their individual sphere of control.<sup>64</sup> For example, a bachelor's life plan may involve marrying and having children with a certain kind of person, but this plan may be curtailed by the autonomy rights of eligible partners. By exercising their autonomy rights over who to marry, these eligible partners may incur obligations that prevent them from marrying the bachelor. Yet we would not say that the bachelor's autonomy rights are violated by the choices of the partners he deems eligible.

An individual's life plan may also be curtailed by a legitimate government exercising its rights and discharging its obligations. When it comes to policy experiments, one obligation is particularly salient. As a condition of possessing a right to rule, governments incur an obligation to, as Raz puts it, "create an environment providing individuals with an adequate range of options and the opportunities to choose them."<sup>65</sup> This obligation

<sup>&</sup>lt;sup>61</sup> Brennan 2016, pp. 88–90. See also Christiano 1996, ch. 1.

<sup>&</sup>lt;sup>62</sup> Lovett and Zuehl 2022.

<sup>&</sup>lt;sup>63</sup> Achen and Bartels 2016, ch. 2.

<sup>&</sup>lt;sup>64</sup> It is for this reason that Raz (1986, ch. 14) emphasizes that self-authorship requires that persons have an adequate range of options and the opportunities to choose from them. I'm grateful to an anonymous referee for calling my attention to this point and for criticisms that considerably improved this section.

<sup>&</sup>lt;sup>65</sup> Raz 1986, p. 418.

stems from the basic interest all individuals have in formulating, pursuing, and revising a life plan of their own making. Policy experiments are important precisely because they help government institutions successfully discharge the obligation to create the conditions for self-authorship.<sup>66</sup> Among the most important ways to create the environment Raz envisions is by ensuring that policy effectively produces autonomy-related outcomes in a population. Yet at the same time, what class size best promotes educational outcomes and what rate of subsidy for health insurance best promotes health are policy questions that bear on entitlements but have no *a priori* answer. These are empirical questions that policy experiments can help answer in an evidence-based and cost-effective manner.

Combining the two points above, the main takeaway is that, despite potentially affecting the course of one's life, non-consensual policy experiments do not ultimately conflict with any specific individual's right to (partial) self-authorship if authorized by a legitimate government. In many cases, government institutions are simply acting on their obligation to promote autonomy as self-authorship in the population they rule over, including those targeted by an intervention as part of a policy experiment.

#### **C. Taking Stock**

My aim in this section has been to highlight how the connection between democracy and autonomy can be leveraged to (partially) justify non-consensual policy experiments. At this stage, I have only argued that democratic authorization achieves one of two ethical objectives associated with informed consent. In the next section, I turn my attention to the second, welfare-based ethical objective associated with informed consent. Those who worry that I have not said enough to rule out the possibility of a benevolent autocrat authorizing a non-consensual policy experiment will find refuge in learning that, though benevolent autocracies are perhaps a real possibility, these governments are unlikely to have the institutional machinery needed to permissibly authorize non-consensual policy experiments.

#### V. DEMOCRACY AND WELFARE

In this section I turn to the second conjunct of P2 and argue that democratic authorization is an ethical mechanism that (b) protects and promotes individuals' welfare interests.

<sup>&</sup>lt;sup>66</sup> See London (2022, ch. 4) for further discussion of this point within the context of healthcare research.

#### A. Acceptable Risk

When it comes to risk assessment, some may be inclined to think informed consent is important because it is never permissible for researchers to impose risks on others without their consent. This is a mistake. Setting autonomy considerations aside, the reason consent is important in clinical settings is due to the significant potential for harm associated with a bodily intrusion. A general right against risk-imposition is also a non-starter. Virtually every form of social organization—including the assignment of rights and obligations—creates unconsented-to risks for individuals.<sup>67</sup> Governments routinely make decisions or implement policies that not only impose risks, but also and knowingly benefit some citizens at other citizens' expense (e.g., trade policy, monetary policy, etc.). Not only do governments sometimes impose risks and set back the welfare interests of some of its citizens, but governments may *justifiably* do so.<sup>68</sup> This is just a consequence of governments exercising their right to rule over policy. After all, it would be miraculous if the exercise of a government's right to rule respected its citizens' autonomy rights but never affected anyone's welfare.

As a general matter, it is uncontroversial for a surrogate decision maker to make risky medical decisions on behalf of an incapacitated person. Surrogate decision makers may also permissibly enroll incapacitated persons in a clinical trial under certain conditions. The reason that family members are often deemed acceptable surrogates is that, due to their close relationship, family members are the most *responsive* to the incapacitated persons' interests. I want to suggest something similar in the case of democratically authorized actors. As I argue below, the reason that democratic authorization makes research risks acceptable is that democratically authorized actors are responsive to those whose interests are potentially affected by a policy experiment.<sup>69</sup>

#### **B.** Democracy and Government Responsiveness

Earlier I discussed the causal link between personal integrity rights protections and democratic institutions. This is not the only empirical basis for an instrumental justification of democracy. Democracy is also valuable because it promotes human

 $<sup>^{\</sup>rm 67}$  See O'Neill (2002, pp. 160–164) for further discussion.

<sup>&</sup>lt;sup>68</sup> See Chwang (2012, pp. 478–480) for related discussion in the context of CRTs.

<sup>&</sup>lt;sup>69</sup> Independent review by ethics committees such as IRBs should still be seen as an additional safeguard when it comes to protecting and promoting individuals' welfare. Independent review can uncover new risks for democratically authorized researchers to consider when deciding whether to proceed with a policy experiment.

welfare. There are different ways which democratic institutions promote human welfare.<sup>70</sup> A particularly illustrative example is the empirical relationship between democratic institutions and famine prevention in LMICs. This empirical relationship has most famously been studied by Amartya Sen, who stresses that the relationship between democratic governance and famine prevention in LMICs is no coincidence.<sup>71</sup> The empirical regularity has an underlying causal basis: government responsiveness. Examining the causal basis for Sen's findings helps address the issue of ultimate concern here: why democratically authorized actors are in the position to conduct non-consensual policy experiments. Per Sen, democratic institutions incentivize those in power to protect and promote the welfare interests of those who put them in power. In explaining the link between democracy and famine prevention, Sen emphasizes the political incentives that operate on governments and on the persons and groups that are in office. Sen writes that in democracies, "rulers have the incentive to listen to what people want if they have to face their criticism and seek their support in elections."<sup>72</sup> For Sen, these political incentives translate into government responsiveness.

William Easterly is another economist who emphasizes the link between democratic institutions and positive welfare outcomes, particularly in LMICs. He stresses that democratic governments are responsive to their citizens welfare because they are *accountable* to them:

accountability is a crucial mechanism in development to ensure that government does good and not ill to those affected by its actions. Under democracy, citizens can use many mechanisms—such as voting, popular protests, and spoken and written criticisms—to penalize governments that are harming individuals (even if it is only a minority of individuals). The same mechanisms reward political actors that do good by, for example, supplying public goods. When such mechanisms work, the government is accountable to its citizens. The opposite of accountability is impunity—the government can do whatever it wants to the citizens without consequences.<sup>73</sup>

What Easterly's helpful synopsis suggests is that democratic authorization is a causal mechanism in addition to an ethical mechanism. Accountability *explains* why democratically authorized actors are responsive to citizens' welfare interests. Under

<sup>&</sup>lt;sup>70</sup> For example, economists have recently established a causal link between democratic institutions and economic growth. See Acemoglu et al. 2019.

<sup>&</sup>lt;sup>71</sup> Sen 1999.

<sup>&</sup>lt;sup>72</sup> Ibid., p. 152.

<sup>&</sup>lt;sup>73</sup> Easterly 2010, p. 1075.

democratic institutions, citizens enjoy the coordinating benefits of centralized political power while ensuring their welfare is not only protected from the exercise of that power, but also promoted.

With the link between democratic institutions and government responsiveness in place, we can now turn back to non-consensual policy experimentation. Democratic governments are in a sufficiently good position to conduct or authorize non-consensual policy experiments because of the political incentives democratically authorized actors face. Democratically authorized actors are already incentivized to design and evaluate policies that promote their citizen's welfare interests. Further, democratically authorized actors are also disincentivized from implementing policy interventions that are *ex ante* harmful or that concentrate risk on some subpopulation. For this reason, democratically authorized actors are also unlikely to conduct or authorize policy experiments that are expected to harm individuals or unfairly impose risks on some subpopulations. This is because those targeted by an intervention have political representatives that must account for their welfare interests to remain in positions of power. And while it is impossible to guarantee no one is ever harmed over the course of a policy experiment (or any research, for that matter), by standers and those targeted by an intervention have the option of seeking rectification through the ballot box or via their elected representatives if their interests are unfairly set back because of a policy experiment.

#### **C. Taking Stock**

I have argued in this section that the causal link between democratic institutions and government responsiveness shows that democratic authorization is an ethical mechanism that (b) protects and promotes individuals' welfare interests. This completes my main argument. Non-consensual policy experiments show respect for persons when the government institution conducting the experiment is democratically authorized to rule over the spheres of policy targeted by the research. We can further say that, just in the same way that informed consent permits others to interact with us in ways that would otherwise be wrong, democratic authorization permits government institutions to interact with us in ways that would otherwise be wrong.

While critics may acknowledge that my argument is sound in the abstract, they will object that it is too idealized for real-world circumstances. Anyone who has the slightest interaction with the real world knows that my characterization of democratic authorization is simplistic. After all, unelected government actors are not directly accountable to citizens so they may not always be responsive to their interests. Further, due to the well documented cognitive constraints alluded to earlier, voters may elect

representatives who fail to protect and promote their welfare.<sup>74</sup> Looming in the background is also the sordid history of research abuses sanctioned by the agencies of (purportedly) democratic governments. Black and brown persons have especially felt the brunt of these abuses.<sup>75</sup>

My account of democratic authorization does still have bearing on the ethical permissibility of real-world policy experiments. First, it is worth noting that the prevailing ethical and regulatory framework for the protection of human subjects in the U.S exists today because of an increasingly democratic US government responding to its past inability to protect the interests of vulnerable populations, which includes racial and ethnic minorities.<sup>76</sup> With respect to the charge of oversimplification, consider an analogy with informed consent. Hardly anyone questions the ethical importance of informed consent in the abstract. Yet when we look under the hood of the consent mechanism, we find that it only has a strong *tendency* to promote positive welfare outcomes and does not necessarily guarantee them. This does not mean that it is impossible for researchers (or anyone, for that matter) to obtain valid consent, much less show respect for persons. Democratic authorization should be seen in a similar light. The accountability mechanism so crucial to justifying democracy's ethical importance also has a strong tendency to promote positive welfare outcomes but does not guarantee them. Unless some other currently feasible ethical mechanism can more effectively reconcile a government institution's obligation to implement evidencebased policies with the need to (b) protect and promote the welfare interests of those targeted by an intervention, we should accept that, for the purposes of conducting nonconsensual policy experiments, democratic authorization shows respect for persons.77

<sup>&</sup>lt;sup>74</sup> Achen and Bartels 2016, ch. 6; Brennan 2016, ch. 2.

<sup>75</sup> Washington 2006.

<sup>&</sup>lt;sup>76</sup> The US arguably became a minimally egalitarian democracy only after the Voting Rights Act of 1965. Public exposure of the Tuskegee syphilis study in the early 1970s led to the National Research Act of 1974. This law established the earliest federal guidelines for human subjects protections as well as the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which produced the Belmont Report (National Commission 1979).

<sup>&</sup>lt;sup>77</sup> To be clear, I am not arguing that, just as we may have to respect an individual's autonomous choice to harm themselves, we also must respect a democratic society's choice to impose harmful policies on its constituents. Epistocrats such as Jason Brennan are correct to point out the flaws with this analogy (Brennan 2016, p. 9). What I am arguing is that it is unreasonable to expect any ethical mechanism to guarantee some of the outcomes its designed to promote, especially when there are currently no feasible alternatives that would do a better job. Epistocrats may ultimately have no issues with administrative government institutions conducting non-consensual policy experiments. However, the role that policy experiments should play in an epistocracy, and whether they could be conducted ethically, remains to be explored.

#### **VI. CONCLUSION**

Despite what I have argued above, let me reemphasize that respect for persons is a necessary but insufficient aspect of ethical human subjects research. Though nonconsensual policy experimentation can show respect for persons, there are reasons why a government institution should perhaps refrain from conducting a nonconsensual policy experiment even if democratically authorized to do so. Informed consent arguably has a third function in human subjects research: (c) promotion of public trust in the research enterprise.<sup>78</sup> There is evidence that not seeking informed consent for clinical research erodes trust in healthcare institutions,<sup>79</sup> which is not to suggest that public trust promotion is a sufficient justification of informed consent requirements.<sup>80</sup> We can say that if an ethical mechanism achieves objectives (a), (b), and (c), then it not only shows respect for persons, but it also promotes public trust in the research enterprise for the right reasons. I have not pursued this more ambitious claim with respect to democratic authorization. Without empirical evidence, it is difficult to determine whether conducting policy experiments without consent decreases public trust in the research enterprise and government institutions, more generally. If it turns out that non-consensual policy experimentation has this effect, then this would be a good reason to halt such experiments. But this would not show that policy experiments are wrong because they violate personhood or fail to show adequate respect. Instead, the onus would be on researchers to convince individuals that policy experiments without their consent are permissible, or perhaps that, like jury duty, it is their civic duty to partake in such research.

#### DISCLAIMER

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<sup>&</sup>lt;sup>78</sup> O'Neill 2002.

<sup>&</sup>lt;sup>79</sup> The most oft-cited example is the fallout from the Tuskegee syphilis study. See Alsan and Wanamaker (2018) for a recent analysis of the study's effects on medical mistrust among older black men.

<sup>&</sup>lt;sup>80</sup> Eyal 2014.

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The author declares that he has no competing interests.

#### REFERENCES

- Acemoglu, Daron. 2010. Theory, general equilibrium, and political economy in development economics. *Journal of Economic Perspectives*, 24 (3): 17–32. https://doi. org/10.1257/jep.24.3.17
- Acemoglu, Daron; Suresh Naidu; Pascual Restrepo; and James A. Robinson. 2019. Democracy does cause growth. *Journal of Political Economy*, 127 (1): 47–100. https:// doi.org/10.1086/700936
- Achen, Christopher and Larry Bartels. 2016. *Democracy for Realists: Why Elections Do Not Produce Responsive Government*. Princeton, NJ: Princeton University Press.
- Alsan, Marcella and Marianne Wanamaker. 2018. Tuskegee and the health of black men. Quarterly Journal of Economics, 133 (1): 407–455. https://doi.org/10.1093/qje/qjx029
- Banerjee, Abhijit and Esther Duflo. 2011. *Poor Economics: A Radical Rethinking of the Way to Fight Global Poverty.* New York: PublicAffairs.
- Banerjee, Abhijit; Esther Duflo; and Michael Kremer. 2019. The influence of randomized controlled trials on development economics research and on development policy.
  Pp. 439–487 in *The State of Economics, The State of World*, ed. Kaushik Basu, David Rosenblatt, and Claudia Sepuvelda. Cambridge, MA: MIT Press. https://doi.org/10.7551/mitpress/11130.001.0001
- Barrett, Christopher and Michael Carter. 2010. The power and pitfalls of experiments in development economics: some non-random reflections. *Applied Economic Perspectives and Policy*, 32 (4): 515–548. https://doi.org/10.1093/aepp/ppq023
- Beauchamp, Tom and James Childress. 2019. *Principles of Biomedical Ethics*, 8th edition. New York: Oxford University Press.
- Bédécarrats, Florent; Isabelle Guérin; and François Roubaud, eds. 2020. *Randomized Control Trials in the Field of Development: A Critical Perspective*. New York: Oxford University Press. https://doi.org/10.1093/oso/9780198865360.001.0001

Brennan, Jason. 2016. Against Democracy. Princeton, NJ: Princeton University Press. https://doi.org/10.1515/9781400882939

Brighouse, Harry. 2006. On Education. London: Routledge.

- Bromwich, Danielle and Joseph Millum. 2015. Disclosure and consent to medical research participation. *Journal of Moral Philosophy*, 12 (2): 195–219. https://doi. org/10.1163/17455243-4681027
- Buchanan, Allen. 2002. Political legitimacy and democracy. *Ethics*, 112 (4): 689–719. https://doi.org/10.1086/340313
- Cartwright, Nancy and Jeremy Hardie. 2012. Evidence-Based Policy: A Practical Guide to Doing it Better. New York: Oxford University Press. https://doi.org/10.1093/acprof:os obl/9780199841608.001.0001
- Christiano, Thomas. 1996. The Rule of the Many: Fundamental Issues in Democratic Theory. Boulder, CO: Westview Press.
- Christiano, Thomas. 2008. *The Constitution of Equality: Democratic Authority and its Limits*. New York: Oxford University Press. https://doi.org/10.1093/acprof: oso/9780198297475.001.0001
- Christiano, Thomas. 2011. An instrumental argument for a human right to democracy. Philosophy & Public Affairs, 39 (2): 142–176. https://doi.org/10.1111/j.1088-4963.2011. 01204.x
- Christiano, Thomas and Sameer Bajaj. 2024. Democracy. In *Stanford Encyclopedia of Philosophy* (Summer 2024 edition), ed. Edward N. Zalta. https://plato.stanford.edu/ archives/sum2024/entries/democracy/
- Chwang, Eric. 2012. Cluster randomization and political philosophy. *Bioethics*, 26 (9): 476–484. https://doi.org/10.1111/j.1467-8519.2010.01874.x
- Cohen, Jessica and Pascaline Dupas. 2010. Free distribution or cost-sharing? Evidence from a randomized malaria prevention experiment. *Quarterly Journal of Economics*, 125 (1): 1–45. https://doi.org/10.1162/qjec.2010.125.1.1
- Cohen, Jessica and William Easterly, eds. 2009. What Works in Development: Thinking Big and Thinking Small. Washington, DC: Brookings Institution Press.
- Council for International Organizations of Medical Sciences. 2016. International Ethical Guidelines for Health-related Research Involving Humans. Geneva, Switzerland. https:// cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf
- Daniels, Norman. 1985. Just Health Care. Cambridge: Cambridge University Press. https://doi.org/10.1017/CBO9780511624971
- Davenport, Christian. 2007. *State Repression and the Domestic Democratic Peace*. Cambridge: Cambridge University Press. https://doi.org/10.1017/CBO9780511510021
- Dron, Louis; Monica Taljaard; Yap Boum Cheung; Rebecca Grais; Nathan Ford; Kristian Thorlund; Fyezah Jehan; Etheldreda Nakimuli-Mpungu; Denis Xavier; Zulfiqar A. Bhutta; and Jay J. Park. 2021. The role and challenges of cluster randomised trials for global health. *The Lancet Global Health*, 9 (5): e701-e710. https://doi.org/10.1016/ S2214-109X(20)30541-6
- Easterly, William. 2010. Democratic accountability in development: the double standard. *Social Research: An International Quarterly*, 77 (4): 1075–1104. https://doi. org/10.1353/sor.2010.0024.

- Emanuel, Ezekiel; David Wendler; and Christine Grady. 2000. What makes clinical research ethical? *JAMA*, 283 (20): 2701–2711. https://doi.org/10.1001/jama.283.20.2701
- Enoch, David. 2020. False consciousness for liberals, part I: consent, autonomy, and adaptive preferences. *Philosophical Review*, 129 (2): 159–210. https://doi. org/10.1215/00318108-8012836
- Eyal, Nir. 2014. Using informed consent to save trust. *Journal of Medical Ethics*, 40 (7): 437–444. https://doi.org/10.1136/medethics-2012-100490
- Faden, Ruth and Tom Beauchamp. 1986. A History and Theory of Informed Consent. Oxford: Oxford University Press.
- Feinberg, Joel. 1986. *The Moral Limits of Criminal Law*. Vol 3: *Harm to Self*. New York: Oxford University Press. https://doi.org/10.1093/0195059239.001.0001
- Flory, Holly; David Wendler; and Ezekiel Emanuel. 2008. Empirical issues in informed consent for research. Pp. 645–660 in *The Oxford Textbook of Clinical Research Ethics*, ed. Ezekiel Emanuel, Christine Grady, Robert Crouch, Reidar Lie, Franklin G. Miller, and David Wendler. New York: Oxford University Press. https://doi.org/10.1093/ oso/9780195168655.003.0060
- Frankfurt, Harry G. 1971. Freedom of the will and the concept of a person. *Journal of Philosophy*, 68 (1): 5–20.
- Fretheim, Atle; Mathilde Flatø; Anneke Steens; Signe Agnes Flottorp; Camilla Jeanette Rose; Kjetil Egill Telle; Jonas Minet Kinge; and Petter Elstrøm Schwarze. 2020. COVID-19: we need randomised trials of school closures. *Journal of Epidemiology and Community Health*, 74 (12): 1078–1079. https://doi.org/10.1136/jech-2020-214262
- Fretheim, Atle; Petter Elstrøm; Cathrine Hagen Julin; Unni Gopinathan; Ingeborg Hess Elgersma; Ragnhild Bø Solberg; and Anette Helleve. 2024. Why were so few randomized trials of public health and social measures conducted during the COVID-19 pandemic? The Norwegian experience. *Trials*, 25 (1): 1–8. https://doi.org/10.1186/ s13063-024-08547-2
- Gelinas, Luke; Alan Wertheimer; and Franklin G. Miller. 2016. When and why is research without consent permissible? *Hastings Center Report*, 46 (2): 35–43. https://doi. org/10.1002/hast.548
- Glennerster, Rachel and Kudzai Takavarasha. 2013. Running Randomized Evaluations: A Practical Guide. Princeton, NJ: Princeton University Press.
- Gueron, Judith and Howard Rolston. 2013. *Fighting for Reliable Evidence*. New York: Russell Sage Foundation.
- Hausman, Daniel M. 2011. Preference, Value, Choice, and Welfare. Cambridge: Cambridge University Press. https://doi.org/10.1017/CBO9781139058537
- Heath, Joseph. 2020. The Machinery of Government: Public Administration and the Liberal State. New York: Oxford University Press. https://doi.org/10.1093/ oso/9780197509616.001.0001
- Hoffmann, Nimi. 2020. Involuntary experiments in former colonies: the case for a moratorium. *World Development*, 127: 1–3. https://doi.org/10.1016/j.worlddev.2019. 104805
- Kahneman, Daniel. 2011. Thinking, Fast and Slow. New York: Farrar, Straus and Giroux.

- Kangas, Olli. 2019. First results from the Finnish basic income experiment, ESPN Flash Report 2019/17, European Social Policy Network (ESPN). Brussels: European Commission. https://research.utu.fi/converis/portal/detail/Publication/41311728
- Karlan, Dean and Jacob Appel. 2011. More than Good Intentions: Improving the Ways the World's Poor Borrow, Save, Farm, Learn, and Stay Healthy. New York: Penguin.
- Locke, John. 1980. Second Treatise on Civil Government. Indianapolis, IN: Hackett.
- London, Alex John. 2022. For the Common Good: Philosophical Foundations of Research Ethics. New York: Oxford University Press. https://doi.org/10.1093/ 0s0/9780197534830.001.0001
- Lovett, Adam and Jake Zuehl. 2022. The possibility of democratic autonomy. *Philosophy* & *Public Affairs*, 50 (4): 467–498. https://doi.org/10.1111/papa.12223
- MacKay, Douglas. 2020. Government policy experiments and the ethics of randomization. Philosophy & Public Affairs, 48 (4): 319–352. https://doi.org/10.1111/papa.12174
- MacKay, Douglas. 2024. The ethics of public policy experiments: lessons from clinical research ethics. Pp. 445–472 in *The Oxford Handbook of Research Ethics*, ed. Ana Iltis and Douglas MacKay. Oxford: Oxford University Press. https://doi.org/10.1093/oxfordhb/9780190947750.013.20
- MacKay, Douglas and Averi Chakrabarti. 2019. Government policy experiments and informed consent. *Public Health Ethics*, 12 (2): 188–201. https://doi.org/10.1093/phe/phy015
- Mill, John Stuart. 1998. On Liberty and Other Essays. Oxford: Oxford University Press.
- Miller, Franklin G. and Alan Wertheimer. 2010. Preface to a theory of consent transactions: beyond valid consent. Pp. 79–105 in *The Ethics of Consent: Theory and Practice*, ed. Franklin G. Miller and Alan Wertheimer. New York: Oxford University Press. https://doi.org/10.1093/acprof:0s0/9780195335149.001.0001
- Miller, Franklin G. and Alan Wertheimer. 2011. The fair transaction model of informed consent: an alternative to autonomous authorization. *Kennedy Institute of Ethics Journal*, 21 (3): 201–218. https://doi.org/10.1353/ken.2011.0013
- Millum, Joseph and Danielle Bromwich. 2018. Understanding, communication, and consent. *Ergo*, 5 (2): 45–68. https://doi.org/10.3998/ergo.12405314.0005.002
- Millum, Joseph and Danielle Bromwich. 2021. Informed consent: what must be disclosed and what must be understood? *The American Journal of Bioethics*, 21 (5): 46–58. https://doi.org/10.1080/15265161.2020.1863511
- Millum, Joseph and Danielle Bromwich. 2024. Respect for persons. Pp. 129–153 in *The Oxford Handbook of Research Ethics*, ed. Ana S. Iltis and Douglas MacKay. New York: Oxford University Press. https://doi.org/10.1093/oxfordhb/9780190947750.013.12
- National Commission (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research). 1979. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Washington, DC: US Department of Health, Education, and Welfare. https://www.hhs.gov/ohrp/ regulations-and-policy/belmont-report/read-the-belmont-report/index.html
- Nuremberg Military Tribunal. 1996. The Nuremberg Code (1947). *BMJ*, 7070 (313): 1448. https://doi.org/10.1136/bmj.313.7070.1448

- Ogden, Timothy, ed. 2017. Experimental Conversations: Perspectives on Randomized Trials in Development Economics. Cambridge, MA: MIT Press.
- O'Neill, Onora. 2002. Autonomy and Trust in Bioethics. Cambridge: Cambridge University Press. https://doi.org/10.1017/CBO9780511606250
- Picchio, Marcos. 2024. What is the standard of care in experimental development economics? *Politics, Philosophy and Economics*, 23 (2): 205–226. https://doi. org/10.1177/1470594X231181655
- Picchio, Marcos. 2025. What role should equipoise play in experimental development economics? *Economics and Philosophy*, forthcoming. https://doi.org/10.1017/S0266 267125000033
- Rawls, John. 1971. A Theory of Justice. Cambridge, MA: Harvard University Press.
- Raz, Joseph. 1986. The Morality of Freedom. Oxford: Oxford University Press. https://doi. org/10.1093/0198248075.001.0001
- Sandel, Michael. 1982. *Liberalism and the Limits of Justice*. Cambridge: Cambridge University Press. https://doi.org/10.1017/CBO9780511810152
- Sen, Amartya. 1999. Development as Freedom. New York: Anchor Books.
- Simmons, A. John. 1979. *Moral Principles and Political Obligations*. Princeton, NJ: Princeton University Press.
- Sreenivasan, Gopal. 2003. Does informed consent to research require comprehension? *The Lancet*, 362 (9400): 2016–2018.
- Sreenivasan, Gopal. 2021. Varieties of minimalism about informed consent. *American Journal of Bioethics*, 21 (5): 66–68. https://doi.org/10.1080/15265161.2021.1906999
- Tanasoca, Ana and Andrew Leigh. 2024. The democratic virtues of randomized trials. *Moral Philosophy and Politics*, 11 (1): 113–140. https://doi.org/10.1515/mopp-2022-0039
- Teele, Dawn Langan, ed. 2014. *Field experiments and their critics: Essays on the uses and abuses of experimentation in the social sciences.* New Haven, CT: Yale University Press.
- US Department of Health and Human Services. 2025. *The Common Rule*. Title 45 (Public Welfare), *Code of Federal Regulations*, Part 46. https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46
- Washington, Harriet A. 2006. *Medical Apartheid: The Dark History of Medical Experimentation on Black Americans from Colonial Times to the Present.* New York: Doubleday Books.
- Wertheimer, Alan. 2010. *Rethinking the Ethics of Clinical Research: Widening the Lens*. New York: Oxford University Press. https://doi.org/10.1093/acprof:oso/9780199743513. 001.0001
- Wolff, Robert Paul. 1970. In Defense of Anarchism. New York: HarperCollins.
- Word, Elizabeth; Johnny Johnston; Helen Pate Bain; B. DeWayne Fulton; Jayne Boyd Zaharias; Charles M. Achilles; Martha Nall Lintz; John Folger; and Carolyn Breda. 1990. The State of Tennessee's student/teacher achievement ratio (STAR) project. Tennessee Board of Education. https://www.classsizematters.org/wp-content/uploads/2016/09/STAR-Technical-Report-Part-I.pdf
- World Medical Association. 2025. World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Participants. *JAMA*, 333 (1):71–74. https://doi:10.1001/jama.2024.21972