Compliance versus Moral Behavior in Human Research: The Need for Compassion and Care

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Author Note

This article is based upon the author's doctoral capstone project, and explores the power domains in human research. The aim is to highlight the role of compassion and care as a means to avoid what is argued as the power and primacy of regulations in human research, which can overshadow the importance of morally directed human research that ought to prioritize the personhood of the research participant. The author is solely responsible for the contents of this article. The contents do not necessarily reflect the position of any of the institutions the author serves. The author has no financial conflicts of interest.

Introduction: The Domains of Powers in Human Research

In human subjects research, hereafter referred to as "human research," the question is raised as to whether compliance with established rules and regulations leads to moral behavior in the treatment of persons participating in clinical investigations. Or, in a reversed formulation of this question, does attention to ethical principles, and intentionally acting consistent with one's moral positions, lead to compliance with the regulatory requirements? It is the first iteration of the question that is of interest to those that are concerned about the treatment of research participants. Thus, the thesis of this article is that for investigators to conduct research with human participants ethically, it is not enough merely to follow the rules for their own sake, or to act only to avoid violating regulations or being non-compliant, which might precipitate possible punitive ramifications. Rather, it is contended that ethical research ought to prioritize the foundational elements of meaningful human interactions, namely, compassion and care for the other. One of the key interactions in research, and the focus of this article, will be on the informed consent process.

It is posited that in research with human participants, and in particular where the informed consent form or the informed consent process is involved in research with humans, there are three overlapping interactive domains, within which there are competing interests. These interests concern first, the power of regulations and enforcement; second, the power of the researcher; and third, there is the power of the person, who is approached to become a research participant. It is the aim of this essay to explore these domains and reflect upon some considerations that may reconcile the tensions between them, while emphasizing that research involving human participants should be first grounded in the building and sustaining of interpersonal relationships that is rooted in compassion and care.

Domain 1: The Power of Rules/Regulations and Enforcement

When Human Subjects Research (HSR), using the conventional phrase, is conducted in the United States, and is regulated by Food and Drug Administration (FDA) (Protection of Human Subject, 2012) and/or subject to Department of Health and Human Services (DHHS)/Office of Human Research Protections (OHRP), known as the Common Rule (Protection of Human Subjects, 2019), there are numerous formal regulations that govern such research. Of specific and critical interest is one of the first touch points in research, namely when an investigator meets with the prospective participant during informed consent encounter. For this activity, there are explicit regulations that establish the requirements for informed consent of research participants, with these rules being statutory and enforceable by the US Government. Information and guidance materials are also available to researchers to provide background context and explanations of the ethical aims of maximizing and protecting research participant rights, safety, and well-being. In these guidance materials, it is noteworthy that informed consent is referred to as a process ("Informed Consent FAQs," 2019), which rightly raises the informed consent interaction beyond the mere informed consent document, to encourage an open communicative engagement between the researcher and participant. Further, the regulations themselves are buttressed by the Belmont Report (The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research, 1978) that articulates the ethical principles that are fundamental to research with humans. These principles include, first, autonomy, in the form of respect for persons; second, beneficence, in the promotion of best-interest/benefit and avoidance of harm; and third, justice and fairness, as considered in the recruitment of participants, as well as the equitable distribution of risks and benefits from research.

Informed consent, as an application of the principle of autonomy, is intended to maximize respect for the research participant, by establishing the conditions necessary for a person to make a voluntary, informed decision to join a study. But, as will be discussed below (Sections 2 and 3), there is a tension that confronts investigators who are concerned about achieving compliance with the regulations, while simultaneously attending to research participants' values of self-determination, best interests, and fairness. There are real barriers to the fulfillment of this ideal, especially as it concerns the question of who is at the center of the informed consent activity and whose interests are being served.

When considering the process of informed consent, it is common to read in human research literature, including research manuscripts and even protocols and research plans themselves, that informed consent from participants has been or is to be obtained ("Informed Consent FAQs," 2019) from the participants studied. Further, Federal regulations themselves and guidance statements use the same word frequently and additionally direct that informed consent to be executed must be legally effective. ("Informed Consent FAQs," 2019) Two issues emerge here. First, regarding obtaining informed consent, it evokes a scenario where at the outset of the informed consent encounter, the informed consent form is presented to the prospective participant, and after he/she has had an opportunity to read the document and presumably have any questions or uncertainties addressed, it is signed and returned to the researcher, to conclude what can be described as a transaction. This process is what is expected per Federal Regulations for the Protection of Human Subjects (21 CFR 50), which subsequently satisfies the statutory requirement for "documentation of informed consent." (Protection of Human Subjects, 2012). An investigator may feel at ease that he/she has acted in

accordance with the regulations, and that the informed consent process has ended as fully and legally compliant: his/her obligations to the rules and participant have been fulfilled.

Second, in attaining informed consent, investigators are enjoined by regulations to assure that the process meets the standard of legal effectiveness. It is reasonable to assume that the adjective "legal" is indeed dominant in the minds of many investigators. To act legally is to act in accordance with established law; to act otherwise, is to act illegally, which may precipitate punishment. Also, the legality of an act presumes its permissibility and adequacy to achieve a specific result, which is to say following a deliberative process per an applicable law implies that in so doing, the act is proper. For informed consent, the first order of legal effectiveness is that a prospective research participant signs and dates the document, and does so prior to the commencement of specified research procedures. But in satisfying the regulatory or legal requirements, it is not unreasonable to question whether this achievement can overshadow or even serve as a surrogate to the moral dimension of the process. In other words, is acting legally the same as behaving morally?

For researchers who are aware of the myriad rules and regulations established by FDA and DHHS, they are also often cognizant of the punitive measures that can be implemented when the statutes are violated or discovered from an inspection (e.g., FDA audit). The punishments can range from restrictions to fines to debarment. If noncompliance findings related to his/her research are identified or reported, an investigator's professional and academic career can be irreversibly damaged. Thus, it is a pragmatic consideration for researchers to maximize compliance, and even to give exclusive attention to the regulations: the professional consequences of non-compliance are too great to disregard. It is interesting to note further that compliance itself is not only an act, but something that can be evaluated and measured objectively by regulatory agencies (e.g., FDA's Bioresearch Monitoring Program (Compliance Program Guidance Manual for FDA Staff, 2008). Simply put, compliance with a regulation can be confirmed with documentation, like a physically producible and properly signed informed consent form, which thus demonstrates achievement of the statutory requirement. Specifically, the degree to which an informed consent exhibits the research participant's signature and date is legally effective, it can be confirmed with other information from the research file.

However, there are other nuanced aspects to the informed consent process that cannot be externally or continuously assessed in real-time, retrospectively, or quantitatively by an inspector. Indeed, other parts of the informed consent discussion (e.g., answering participant questions, assessing comprehension, assuring voluntariness, etc.) are in most encounters left to the investigator, such that he/she alone determines the adequacy or satisfactoriness of a participant's understanding of the research to be undertaken and his/her willingness to enroll. Further, at this time, the consenter can affirm in his/her mind that the complete consent process was not just adequate, but fully attendant to the ethical principles both articulated in the regulations and consistent with his/her moral code. But beyond the isolated researcher-participant encounter, objectively affirming compliance with these subjectively interpreted activities cannot be easily assessed by a third party. Moreover, it would be very difficult to evaluate an investigator's internal moral comportment or his/her intentions during the informed consent process, and most likely impossible from a retrospective assessment. In summary, the moral quality of the consent process is exclusively between the consenter and the consented, with only the researcher being in the position to apply his/her motivations and moral discernment. The second and succeeding sections should present the various questions and aspects of the topic being explored.

Domain 2: The Power of the Researcher

Investigators in research using humans are empowered by their professional roles, which might also be potentially influenced by his/her gender, education, socio-economic status, and race. In our society, the authority of the clinical researcher or scientist is readily assumed and accepted as legitimate. Moreover, when a clinical investigator is also a physician, research on his/her patients (with an existing physician-patient affiliation) may also be argued to overlap with a parallel researcher-participant relationship. In human research the investigator has increased power and influence over the prospective participant: he/she is the expert. Further, when an investigation is introduced to the potential participant and an informed consent form is presented, the researcher holds a *de facto* position of power: he/she knows the research (the hypothesis, the new drug being studied, the medical procedures involved, etc.). There is what could be described as an asymmetrical power relationship, an imbalance that may not be remediated due to presumed inherent differences between the researcher and the participant.

An additional facet of the power of the researcher is the responsibility to act in a manner that is consistent with standards of practice that are universally accepted by that person's respective profession (e.g., physicians, nurses, psychologists, etc.). To identify oneself as a professional, he/she is expected to have requisite education, with a verifiably high level of competency and technical expertise. In addition, provisions are articulated in professional codes that members take part in specialized training to maintain, refine, or advance their respective skill-sets. For researchers conducting investigations on human persons, along with applicable professional expectations they are mandated by regulations to be "qualified and experienced." (Responsibilities of Sponsors and Investigators, 2018). Assuming successful achievement of professional status, a researcher with requisite expertise and training may project power in the form of an unquestioned or unassailable assurance to participants that he/she is both competent and skilled. Additionally, the investigator is thus assumed to be both authoritative and in control, as a dominant force that is typically societally legitimated and accepted. And, this power is often accompanied by public assumption that the professional also has a high moral character.

It is interesting to mention that along with the power of the researcher, there is also the power of research itself: Are pragmatic considerations and regulatory compliance often a priori considerations in human subjects research (using the common phrase)? Traditionally, the answer would be, yes. The real-world truism for the pharmaceutical and medical device industries, Federal funders, and foundations, is that *human subjects research must include human subjects*. Therefore, the success of a clinical trial depends on adequate enrollment, which for researchers is dependent on funding or driven by the benefits of academic promotion or publication demands. These and other forces can insinuate many pressures. It is not suggested that investigators under such pressures are given over to conduct non-compliant or unethical research, but the stresses from many quarters are real. Performing research in a manner compliant with regulations is critical for investigators as they intend to make their own contributions to science, generalizable knowledge, and human health and well-being at large.

Domain 3: The Power of the Research Participant, as Person

For this part of the discussion, it should be emphasized that the participant's power, as explored below, can vary across a wide continuum. Specifically, research participants that are children have diminished legal power by virtue of not being a legal adult. Also, participants who

are incarcerated may be argued to have reduced power, secondary to their being in a restricted penal environment, which often is characterized as being potentially coercive. Lastly, research participants who have diminished decisional capacity (e.g., due to mental illness) have decreased power, which has to be delegated to a legally authorized representative to advocate for the person's best-interests. In short, there have been and are many research participants with various challenges that render them especially vulnerable and disempowered. As such, additional regulatory protections, along with expanded considerations from Institutional Review Boards (IRBs), have been established. Thus, for the purposes of this article, research participants are those individuals commonly regarded as non-incarcerated adults that have presumed decision-making capacity.

Regarding the power of the participant, there are two basic aspects, namely the pragmatic or objective value to research, and the power that rests in the research participants' intrinsic personhood. For the first, there is the empirical power that research participants have by virtue of the fact they are necessary for research to take place, for new drugs and devices to be developed, and for new knowledge to be generated about human health, disease, and wellness. However, for the second facet, in the history of human research, persons experimented upon have in many situations been overtly and tragically reduced to mere objects to be studied, often for nefarious and unscientific ends. History is replete with events where persons have been relegated to the status of a thing, with only scientific use-value, reduced to a number as part of an "n" needed to achieve statistical significance, or belittled to a demographic data point. With the reduction or elimination of these persons' humanity, unscrupulous scientists conducted their research driven by a perverse rationale that the results of their experiments took priority over the value of the persons on whom they experimented. As is well known, in the name of science, people have been treated in abjectly immoral ways, where their power was taken away, as they were exploited, degraded, injured, denied care, and even murdered (e.g., the Nazi Medical Experiments, the USPHS Syphilis Study at Tuskegee, and many others). And, it is indeed the recognition of this troubling history, that research regulations and guidance have been developed in the United States and other nations to affirm and safeguard the humanity of research participants.

Yet, in referring to the regulations, the current Common Rule (45 CFR 46), and accompanying guidance, can be seen to render the potential research participant as a passive receiver of information, to whom the responsibility is exclusively delegated to the investigator to provide material – which the investigator deems relevant – to the prospective participant. In other words, although critical to the one side of the investigator-participant dyad, the guidance (and its recommendations) does not explicitly or adequately acknowledge the power of the participant. Put another way, in simply relying on the legal requirements, an investigator may believe that he/she gives power to the participant by providing information that "…is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research." (Revised Common Rule, 2019). What is at issue here is the risk in practice that a prospective participant will be put into a position where he/she must understand the research in the investigator's terms. In other words, the responsibility falls to the participant to understand the research: the purpose, procedures, risks, benefits, etc.

It is necessary to re-iterate that the power of the research participants is intrinsic and defining of his/her fundamental personhood. As noted above regarding the ethical principle

of autonomy, every person is imbued with the autonomous ability to act in a way that is self-determined and freely directed toward his/her best-interest. Even with varying degrees of mental capacity, emotional influences (e.g., fear, uncertainty, unrealistic optimism in the proposed outcomes of a study, etc.), and other characteristics of an individual, autonomy nonetheless exists, even if in diminishing degrees. Participants have the power to agree to be in a study because they are driven by the desire to join, to contribute to the advancement of knowledge, or because it may help themselves or others. Equally, they also have the power to decline, and to do so freely for their own reasons. And it ought to be the case that at all times researchers recognize that participants have the essential power to choose to remain in a study, or to withdraw at any time. The research participant is always greater than the research, and should not have his/her personhood subjugated by the power of the researcher or the research itself.

Conclusion: The Power of Compassion and Care

To summarize the above, in the power domains of research regulations and the researcher, both are characterized by rules of behavior that are held to be by nature compulsory. Further, legal and professional requirements are externally established, with oversight mechanisms built in to assess, confirm, and enforce compliance. These requirements are held to have objective validity and force, with an *ex post facto* binary outcome: either one is in compliance or one is not. Further, like research itself, satisfying regulatory requirement is beholden to data and evidence that can be surveilled and analyzed. But what of moral behavior in human research and the moral status of research participants? Are these amenable for scrutiny under the gaze of an inspection apparatus and measured to gauge adherence to a *quasi* legal requirement? Because the informed consent process, not unlike the encounter between a physician and patient, is by-and-large a *private* interaction, it is not feasibly amenable to *objective* or *analytically* focused observation by a third-party, or in the guise of a quality-control exercise.

Thus, the power of the research participant *qua person* ought to be intentionally and reflectively valued by the investigator, and construed as constitutive to a deeper relationship that is characterized by *compassion* and *care* for the other. In research, compassion, etymologically defined as *suffering with*, would manifest in the relationship between the researcher and the participant. For example, a researcher, observing that a prospective participant is fearful or distrustful, would be sensitized to the person's concerns. The participant's issue would necessarily take priority over stark efforts to recruit the person, whereby the researcher would listen to what that person's feelings are. Further, the responsibility of the investigator would be not to remediate or dismiss such feelings, or overwhelm the concerns with information; but rather the researcher would be cognizant of these matters as being part of participant's whole being. *Caring*, by definition to have concern for or interest in another, is complementary to compassion. Here, a researcher would additionally have an abiding and substantial interest in the participant *as a person*, who has an identity, family, culture, and history, i.e., the participant's story. A relationship authentically based on caring would never diminish an individual to a research *subject* (i.e., *object*).

But how does a researcher develop and apply these attitudes? Can they be displaced or misdirected by the demands of legal and professional requirements? Scientists, medical professionals, and clinical investigators are educated and trained in their respective fields, earn credentials, and practice within the boundaries established by professional codes and legal statutes. Some may even have training in human research *per se*. But is there an equivalent

programmatic approach to building one's moral character? A person can be taught ethical principles, bioethics, or specifically *research ethics*. What is the role of a researcher's internalized or personal moral convictions, orientation and conscience? It is not to discount facilely that a researcher has his/her personal morality already in place, which guides that person to act consistently with that orientation. However, as discussed above, at times, the power of regulations can overshadow moral judgment, such that achieving valid results in an investigation and doing so in strict, rote compliance with legal requirements defines the research activity, perhaps to the detriment of the personhood of the research participant.

Thus, for consideration is the place of compassion and care in human research. Like morality, these are not amenable to being solely the content of a training manual. Moreover, as elements of moral behavior toward others, are compassion and care not compelling for their own sake? Regulations and laws are obligatory because of their power, which are reinforced in their being acceptable and enforceable. To comply with rules effectively assures legal and scientific acceptance based on agreed upon standards. And the ethical principles in human research explained above are fundamentally important to articulate moral values and moral experience and judgment. But the mere intellectual or rational comprehension of them is not complete without the subjective recognition of the other person, namely, the research participant. Ethical rules and principles become like regulatory rules and regulations when compassion and care are not part of one's relationship with the research participant, as another person essentially infused with his/her own power. Along with the concept of legal effectiveness is a parallel notion of *ethical effectiveness*. Does this approach permit and encourage the integration of compassion and care?

Unfortunately, ethical effectiveness, like legal effectiveness, is not necessarily sufficient in and of itself during the research-participant encounter. Although open to debate, in only acknowledging the ethical principles, it still might not occur that the deep and subtle dimensions that distinguish the research participant as an individual person are addressed. A tendency may be argued that investigators might only understand that the ethical principles themselves, potentially detached from the participant *as person*, are to be sought or achieved as a fixed outcome. For example, the act of obtaining informed consent would be performed to satisfy the objective ethical requirement to promote individual *autonomy*. Autonomy, in this example, is sought for itself, a *res extensia* to the person, possibly devoid of the nuanced implications that would necessitate compassion and care.

To conclude, in thinking about the power domains, the charge then for investigators is to listen not only to their own internal moral voice, but also, and most importantly, they also ought to strive to harness compassion and care in order to feel the personhood of the participant, and not to rely on the one dimensional achievement of compliance as a primary accomplishment, devoid of the moral perspective and the value of the participant as person. Endeavoring in this way builds an enduring relationship that realizes that the researcher and participant are in fact on the same journey together.

References

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Editor's Note

The previous article is an excellent example of the tension between normative ethics (what one *ought* to do) and virtue ethics (what a morally good person does). Normative ethical standards are often codified in lists of rules. You shall do this; you shall not do that. Most professional organizations have such lists, and it may be argued that our law codes embody normative ethical standards. But what moral force empowers such rules? Why *ought* we to keep them? Are we morally obligated to keep rules because they are rules? Alternatively, does keeping rules ensure that we are acting in the highest moral sense? The article above argues that there are aspects of morality that transcend simple rule keeping. Aristotle would agree. In *Nicomachean Ethics*, Aristotle focused his attention on the actor rather than the action. In other words, he was more interested in good people than in good rules. He asked what makes people virtuous and how do they act when they are? Such discussions are long overdue. Ethical issues about research and healthcare are too complex and important to be distorted downward to a list of do's and don'ts. In fact, all of these issues are at the very heart of our new Open Forum section. In each of the section's articles in this edition and those to come, we are invited and urged to dive into these deep and abiding issues.