# Foreword

## Reflections on *Belmont* at Forty

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The *Belmont Report* turned 40 in 2019, and, just as adults ask themselves existential questions as they age, so, too, was there much handwringing about the relevance, vitality, and staying power of the *Belmont Report* on the occasion of its milestone birthday.

Like adults facing a midlife crisis, the academic fields of bioethics and public policy—among others—took the opportunity to question where we are, how we got here, and whether we should have made different choices. This generated a flurry of scholarly think pieces about the *Belmont Report*, exploring the impact of the document and ruminating about its applicability as it heads into its fifth decade.* Although a good number of the commentaries were complimentary about *Belmont*'s staying power, others called for a reexamination of the principles (and even of principlism as an approach to ethical decision making). Perhaps not unsurprisingly, common themes emerged in the *Belmont*-at-40 literature oeuvre.

First, it seems there is a general (although not universal) consensus that the ethical principles of respect for persons, beneficence, and justice have provided a valuable framework for moral decision making regarding human research and the protection of research subjects' rights and welfare. Indeed, these principles have become downright canonical in research ethics scholarship, while at the same time serving as a mantra for legions of IRB members and staff, who do the hard work each day of trying to operationalize their meaning and intent.

Second (and somewhat paradoxically), there is both a reverence for the historical significance of the document and a willingness to question the process of its creation and the outcomes of the exercise to produce it. Each of these impulses merits further consideration.

With regard to process, it is worth recalling the circumstances under which the commission that wrote the report was established. In the wake of concerns in 1972 about the now notorious Public Health Service–funded study of syphilis in the "negro" male, the U.S. government set about designing a new ethical, legal, and regulatory landscape for the protection of human research subjects. In a visionary attempt to avoid putting the cart before the horse, this redesign process began, not with a rush to produce regulations, but with an effort to establish the fundamental principles that could provide a foundation for the policies, rules, and practices that would follow.

Because the commission's first meeting took place at the Belmont Conference Center in Elkridge, Maryland, the final report was given the name of that

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*One of these was co-authored by Kyle Brothers, Aaron Goldenberg, and me. The drafting of that article heavily influenced my thinking about this essay.

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center: "Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research."

By today's standards, the group charged with writing the report was exceedingly homogeneous and therefore did not reflect the diversity of the U.S. population or the various constituencies we currently would expect to be given a seat at the table for such an undertaking. Indeed, if such a commission were chartered today, we would expect to see a very different roster. That said, we in the field of research ethics owe a debt of gratitude to the architects of the *Belmont Report*, who wrestled valiantly with some of the thorniest conflicts, challenges, and dilemmas of that time—many of which continue to characterize the enterprise of human research today.

Nevertheless, there has been much questioning of and reflection on the report's drafting and ultimate conclusions. Was the process sound? Were the "right" voices in the room? Might we need additional principles today? These have not so much constituted a critique of the *Belmont* principles *per se* but rather are evidence of the ways in which the public's perspectives and values have changed since the report was first published in 1979.

Numerous societal changes have influenced the myriad ways we think differently today about human research protections than we did 40 years ago. These include skepticism of authority, the imperative to "do it yourself," a more sophisticated appreciation for human diversity and intersecting forms of oppression and inequality, and evolving notions of ownership (both with regard to data and biological specimens). There also have been changes in the research enterprise itself.

Some of these changes may be attributable to the development of new technologies. The rapid expansion of multisite research, which brought with it new challenges related to data sharing and storing of specimens, has been made possible in large part due to the opportunities for collaboration created by the internet. However, societal changes cannot be explained by the availability of new technologies alone. Consider, for example, emerging practices like the inclusion of community members in research oversight, expanded efforts to make research data publicly available, and the participation of patient advocacy groups in collecting and sharing data. To some extent, new technologies made these activities possible, but they also reflect a change in cultural values.

Patients are now far less likely to accept a "doctor knows best" approach and instead expect that healthcare providers will welcome shared decision making. This trend toward leveling the power differential between professionals and their clients is not limited to medicine. To varying degrees, professionals in many fields—lawyers, accountants, realtors, bankers, etc.—have begun to shift toward playing an advisory role to their clients. Given this shift, it should not be surprising that researchers have begun to adopt—and research participants have begun to expect—approaches to research that encourage study participants to take a more active role in the research process.

As times have changed, IRBs have had to (and will continue to) navigate an ever-evolving landscape of new technologies and shifting cultural values. And, like the middle-aged parent of a teenager who must adjust to the sounds of unfamiliar musical artists and a later curfew, those of us responsible for protecting human subjects' rights and welfare must learn to apply the *Belmont* principles in the context of today's world.

The enduring relevance of *Belmont* speaks volumes about the elegance of the principles and their applicability despite changing norms. However, the weight given to each of the principles has shifted over time. For many years, respect for persons was treated like the primary principle to be observed by IRBs and researchers, with beneficence and justice playing supporting roles. In today's context, it is more common to think about the three principles as points on a triangular plane, resting precariously on a fulcrum. As the IRB or researcher attempts to maximize one principle, it becomes elevated over the other two. Thus, an emphasis on beneficence can reduce justice. Under the best circumstances, IRBs and researchers can strive for something closer to balance by attending to all three principles.

Our understanding of the principles also has shifted over time. The evolving interpretation of the justice principle provides a keen example. The commissioners who framed the *Belmont Report*, responding to legitimate and urgent concerns about the exploitation of vulnerable populations, such as those enrolled in the aforementioned PHS-funded syphilis study, focused on the aspect of justice that has to do with avoiding exploitation of vulnerable populations. Accordingly, the report's discussion of the justice principle asserted that, "the selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied."

Although the principle of justice still requires fairness, modern IRBs do not and should not focus exclusively on the aspects of justice that have to do with avoiding exploitation; indeed, most research ethicists now emphasize the importance of avoiding the unjustified and unfair *exclusion* of certain populations from research. We recognize now that the paternalistic "protection" from research that for many years kept children, so-called "women of child-bearing potential," and members of minoritized groups out of studies resulted in research findings that often were not broadly applicable and that neglected the specific and unique health needs of large segments of the population.

A close reading of the *Belmont Report* reveals that its framers understood the complexity of the justice principle, evidenced by that fact that they encouraged us to think about fairness in a variety of ways: "injustice arises from social, racial, sexual and cultural biases institutionalized in society. Thus, even if individual researchers are treating their research subjects fairly, and even if IRBs are taking care to assure that subjects are selected fairly within a particular institution, unjust social patterns may nevertheless appear in the overall distribution of the burdens and benefits of research." It would be hard to argue that these words are any less relevant in today's world.

We can thank members of patients' rights, civil rights, and various liberation movements for drawing attention to the aspects of justice that require intentional and deliberate inclusion of diverse populations in research to achieve fairness. We also should applaud the many IRB members and staff who, over the years, have worked tirelessly to honor the spirit of the *Belmont* principles while applying them in the context of changing cultural norms.

This is no easy feat. To serve on an IRB is a great responsibility. Doing it well requires intellectual curiosity, good judgment, and a genuine desire to promote high-quality research for the benefit of society. IRB members must deftly execute their duty to protect subjects' rights and welfare and a concurrent obligation to avoid unnecessary impediments to important research that sometimes are created by excessive institutional risk aversion. An openness to learning is essential, which is why books like this one are so helpful—not only for "onboarding" of new IRB members and staff but also as a reference manual to help guide decision making when ethically challenging questions arise in the review and oversight of human research studies.

The regulations that eventually were written after the publication of the *Belmont Report* promulgated the belief that a group of thoughtful people, working together to think about and resolve moral questions and ethical dilemmas, could arrive at more sound and appropriate decisions than a simple bureaucratic form or administrative procedure. And, for the most part, this belief has borne fruit. Communities of researchers, scholars, public policy experts, research subjects, and others have, over the years, built a community concerned with advancing best practices for IRBs and promoting the highest ethical standards for the conduct of research. By publishing and periodically updating this book, PRIM&R contributes to those efforts.

But continuous improvement is never done. So, having been subjected to reexamination at its 40th birthday, the *Belmont Report* now stands firmly in mature adulthood—older, wiser, and more comfortable with the ambiguities of life, ready for the inevitable challenges ahead, and open to the potential for reflection, change, and reinvention.