212 Carnegie Center / Suite 301
Princeton, NJ 08540
609.945.0101
www.wcgclinical.com

December 12, 2019

The Honorable Elizabeth Warren
United States Senate
309 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Bernard Sanders
United States Senate
332 Dirksen Building
Washington, D.C. 20510

The Honorable Sherrod Brown
United States Senate
503 Hart Senate Office Building
Washington, D.C. 20510

Dear Senators Warren, Sanders, and Brown:

I am writing to confirm that WCG has received your letter dated November 15, 2019, and that we share your desire to ensure that human subjects who participate in clinical trials are properly protected.

WCG was the first commercial Institutional Review Board (IRB), and in the more than fifty years since our founding, we have set the standard for protecting human subjects in clinical research in the United States. In both the public and private sectors, we have long been known as the "gold standard" in the performance of ethical review. Our practices make certain that we scrupulously adhere to all regulatory requirements, that no panelist has any financial interest in any study that they review, and that there are no conflicts of interest in our mission to protect human subjects.

To give you a further sense of our Company, let us share with you our mission statement:

> It is the mission of WCG to provide the people who perform clinical trials with the highest quality of services to accelerate the scientific advancement of human health, while ensuring that the risks of progress never outweigh the value of human life. [1]

We fulfill that sacred mission in a highly regulated environment, in which we operate consistently and transparently with -- and go beyond the requirements of -- the Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP). Our IRB panelists undergo continuous evaluation and

[1] *About WCG*, WCG, https://www.wcgclinical.com/about/ (last visited Dec. 6, 2019).

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training consistent with our standard operating procedures and practices. These practices are subject to regular audits by the FDA and the Association for the Accreditation of Human Research Protection Programs (AAHRPP).

Our senior compliance executives have been invited to join and voluntarily serve on a number of ethics advisory committees including the Secretary's Advisory Committee on Human Research Protections (SACHARP), an advisory committee of the U.S. Department of Health and Human Services. In fact, those WCG executives have donated a combined total of more than twenty-four years to this important government service.

In addition, we have a number of other activities that highlight our commitment to the public good. We have a program that provides expanded access IRB reviews for patients who have no treatment alternatives other than receiving emergency experimental drugs. WCG provides this service directly to the patients and at no charge to the patients or their providers benefitting hundreds of patients over the last several decades. As another example of our long-term commitment, we have supported and trained, in a WCG-subsidized program, more than 190 visiting international fellows from more than 25 countries. These clinicians spend up to six months at our offices learning the highest standards of ethical review. They return bringing these best practices to clinical trials conducted in their countries. We are proud that our fellows are ensuring that human research subjects in these developing countries also receive the highest standards of protection.

We truly appreciate and share your concern about protecting patients. It is what has animated our company for more than fifty years and what inspires our employees to work with tireless commitment to fulfill our mission. We hope that the information we have provided is of assistance to you in understanding our goals.

Sincerely,

Donald Deieso, Ph.D
Executive Chairman & Chief Executive Officer
WCG Clinical