Chairman Johnny Isakson
Senate Veterans Affairs Committee
412 Russell Senate Building
Washington, D.C. 20510

Chairman Mark Takano
House Veterans Affairs Committee
B234 Longworth House Office Building
Washington, DC 20515

Ranking Member Jon Tester
Senate Veterans Affairs Committee
412 Russell Senate Building
Washington, D.C. 20510

Ranking Member Phil Roe
House Veterans Affairs Committee
3460 O'Neill House Office Building
Washington, D.C. 20024

May 13, 2019

Dear Chairman Isakson, Ranking Member Tester, Chairman Takano, and Ranking Member Roe:

We write to ask for your help in creating a more effective approval and oversight process for industry-sponsored clinical research at the Department of Veterans Affairs (VA). We strongly believe that the VA can become a leading partner in the development of new therapies and diagnostics. The VA should take action to become "100 days faster" in clinical trial startup, beginning with finalizing and implementing new VA policies on the use of commercial institutional review boards (IRB), and we ask for your support in that goal.

Clinical trial startup at VA sites averages more than 100 days longer than at non-VA sites, according to data from contract research organizations. For Veterans suffering from post-traumatic stress disorder, traumatic brain injury, hearing loss, alcohol and other substance disorders, cancer, and other conditions for which a clinical trial may be the next or only treatment option, these delays can restrict their access to these opportunities. Furthermore, these lengthy timelines increase costs for those who partner with the VA and discourage others from approaching the VA altogether. Our organizations have been working with the VA to develop and advance reforms to streamline the approval process, identify and propagate best practices, and develop true consistency in the administration of industry-sponsored clinical trials at the VA. We believe that with your help in bringing about these changes, the VA can decrease the average site startup time by 100 days within three years, which would put them on par with other world-class research institutions. With each reform to clinical trial startup, more VA facilities will be able to attract clinical trials, making cutting edge treatments available to a wider cross-section of Veterans across America.

As a first step towards "100 days faster," which we suggest the VA adopt as a reform mantra, we ask that the VA take all steps necessary to permit the use of commercial IRBs accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). This policy revision would allow for a more predictable and timely IRB process. IRB reviews ensure that clinical trials abide by clear ethical guidelines and protect the well-being of research participants, but sponsors need the reviews to be prompt and consistent. Despite earnest efforts by many within the VA to standardize and improve this regulatory process, it continues to be a source of major delays in the clinical trial startup process. Based on our years of sponsoring, facilitating, and tracking clinical research, we have found that VA IRBs are slower overall, including many cases where VA IRB review delays have prevented a VA site from completing all

necessary start up activities in time to participate in a study. In 2016, the VA opened the Central IRB to industry sponsored multi-site trials on a pilot basis. However, the Central IRB continues to lag far behind the standard review and approval timelines of other IRBs. In fact, some multi-site trial sponsors have chosen to forego VA Central IRB approval and rely on VA local IRBs in the hopes of getting one or two of the more efficient sites approved rather than wait on the Central IRB approval for all sites.

Over the past two years, the VA Office of Research and Development (ORD) has been exploring policy changes to allow the use of commercial IRBs as another option to local IRBs or the VA Central IRB. We support this effort, but are very concerned as to the delay in making changes. We understand that VHA Handbook 1200.05 specifically prohibits the use of commercial IRBs. We ask that Congress require that by June 30, 2019, the VA complete all necessary policy revisions and implement steps to allow the use of commercial IRBs accredited by AAHRPP.

Expanding IRB options for VA investigators and research sponsors is an important step toward "100 days faster" and ultimately to a more effective approval and oversight process for industry-sponsored clinical research at the VA. We look forward to working with you on this and other important clinical trial startup reforms in order to achieve "100 days faster."

Sincerely,

Coalition to Heal Invisible Wounds
Washington, DC

Advantagene, Inc.
Auburndale, MA

Association of Clinical Research Organizations
Washington, DC

Cohen Veterans Bioscience
Cambridge, MA

LUNGevity Foundation
Chicago, IL

Military Veterans Project
Topeka, KS

National Association of Veterans' Research and Education Foundations (NAVREF)
Washington, DC

NAMI Montana
Helena, MT

Navy SEAL Foundation
Virginia Beach, VA

PPD
Raleigh, NC

Prostate Cancer Foundation
Santa Monica, CA

Veterans Against Alzheimer's
Chevy Chase, MD