Statement for the Record

Prepared by the National Association of Veterans' Research and Education Foundations

Prepared for the Subcommittee on Health

House Committee on Veterans' Affairs

United States House of Representatives

Regarding Steps to Improve VA's Clinical Trial Start-up Practices

June 26, 2019

The National Association of Veterans' Research and Education Foundations is the 501(c)(3) nonprofit membership organization of research and education foundations affiliated with Department of Veterans Affairs (VA) medical centers. These nonprofits, also known as the VA-affiliated nonprofit research and education corporations (NPCs), were authorized by Congress under 38 USC §§7361-7366 to provide flexible funding mechanisms for the conduct of research and education at VA facilities nationwide. Currently, there exist 81 NPCs supporting research and education activities at almost 100 VA medical centers.

NAVREF's mission is simple—we exist to advance the success of the NPCs. Together, NAVREF and the NPCs serve not only the Veteran, but the team of VA research and educational experts committed to improving the lives of Veterans. Ultimately, NAVREF envisions a nation in which Veterans receive the finest care based on innovative research and education. We believe that by working closely with Congress, VA leadership, NPC boards and leaders, and the great researchers and scientists working across the country in VA medical centers that our lofty vision can be achieved.

NAVREF has been encouraged by the leadership of Dr. Carolyn Clancy throughout her various roles across the Veterans Health Administration, but we are especially pleased to have her leading the recently established office of Discovery, Education, and Affiliate Networks, which oversees research and development. We strongly support the transformation efforts of VA's Chief Research & Development Officer, Dr. Rachel Ramoni, and the three high-level priorities she established last year—enhancing access to high quality clinical trials, driving substantial real-world impact, and putting VA data to work for Veterans. We look forward to continued collaboration with Dr. Clancy, Dr. Ramoni, and the first-rate team they've assembled at the Office of Research and Development (ORD) to address these priorities.

NAVREF's top priority initiative is to bring more clinical trials to Veterans in VA medical centers. It is critical that Veterans have the same level of access to these cutting-edge therapies as their counterparts outside the VA. In some therapeutic areas—most prominently in oncology—clinical trials are the standard of care, yet many Veterans do not have access to this life-altering research.

In December 2017, ORD and NAVREF embarked on a new effort to increase Veterans' access to clinical trials. The initiative, titled Access to Clinical Trials for Veterans (ACT for Veterans), kicked off with a Stakeholder Summit in April 2018 which brought together representatives from industry, VA Central Office, VA medical centers, patient advocacy groups, and the NPCs to participate in facilitated discussions centered around study start-up. It was important for all of us to hear industry's perspective on doing business with VA, so that we could understand where we needed to direct our energy to effect meaningful change. Since that initial meeting, five top priorities were identified, and workgroups were commissioned to address these priorities. NAVREF continues to solicit external stakeholder feedback at every step of the process. In February 2019, a Workgroup Summit was held in Washington DC which allowed the five workgroups to come together, present their respective products, and receive feedback on those deliverables.

Throughout this effort, ORD has been a steady partner, devoting time and manpower to every workgroup and completing additional tasks in support of ACT's objectives. But ORD cannot do this alone. Properly supporting clinical research requires a much broader effort across VA and VHA. One of the most important steps taken over the last ten years to support industry-sponsored clinical trials at VA medical centers was the establishment of the Specialty Team Advising Research (STAR) within the Office of General Counsel. Prior to the establishment of STAR, all legal reviews of research agreements (such as Non-Disclosure Agreements and Cooperative Research and Development Agreements) were handled by regional attorneys who had broad portfolios of higher priority matters and limited experience handling research issues. Timelines for review were understandably lengthy and unpredictable, such that some pharmaceutical companies were unwilling to work with VA sites. The establishment of STAR—a dedicated team of attorneys specializing in medical research matters—quickly reduced the backlog of agreements and led to predictable and reasonable timelines.

Similar to the legal delays that occurred ten years ago, clinical trials are now challenged by the unpredictability of reviews from the local offices of information security and privacy. Most VA hospital-based information security officers and privacy officers have limited expertise in research, which has many unique aspects that differ from the typical health care delivery setting. Therefore, they require additional time to review research proposals and frequently give inconsistent answers to the same question from site-to-site. This unpredictability causes delays and creates uncertainty among pharmaceutical companies seeking efficient, consistent trial sites. The solution for information security and privacy reviews should be the same as for legal reviews—centralization and standardization.

In 2018, the Office of Information Technology established a team of three Information Security Officers (ISOs) at the VA Central Office to assist local ISOs with clinical research approvals. This is a good first-step to clearing the obstacle currently faced at local sites with ISO reviews. **NAVREF urges VA to make permanent the Office of Research Reviews within OIT and to create a similar permanent office for privacy reviews.** These offices need to be given the people, resources, and authority necessary to accomplish their intended mission of supporting research activity and reducing review timelines so that industry sponsors are compelled to bring clinical trial opportunities to Veterans at VA medical centers.

Another primary component of extended start-up timelines at VA facilities is the use of VA institutional review boards (IRB). IRBs play a critical role ensuring human research is conducted ethically and appropriately without causing harm to research participants. VA IRBs have a proud history of high-quality reviews that put the veteran's well-being first. However, the extended timeframe for these reviews exceeds typical industry expectations and can lead pharmaceutical firms to avoid VA sites. The Department of Defense faced a similar dilemma several years ago and successfully addressed the situation by allowing the use of commercial IRBs. **VA should do the same and allow the use of commercial IRBs.** The commercial IRB industry has demonstrated the highest standards of protections for patients—research-based risk protections, health information privacy protections, and information security protections. They undergo rigorous accreditation processes in order to safely and effectively conduct timely research reviews across the United States and the world.

As part of the ACT for Veterans initiative and to comply with the single Institutional Review Board (IRB) review mandate that will take effect on January 20, 2020, ORD is seeking policy change to allow for the use of commercial IRBs. Within VA, a risk assessment will need to be completed to determine whether Veterans' health information should be shared with commercial firms outside of the VA information network. As stated previously, commercial IRBs have a strong history of protecting patient data and privacy—they could not survive without privacy and security as foundational elements of their business. The DoD has acknowledged that commercial IRBs are sufficiently trustworthy to be considered minimal risk when it comes to handling the health information of military personnel. VA should make the same determination. The importance of giving Veterans access to potentially life-changing medical therapies should be heavily weighted when conducting these risk-reward assessments.

SUMMARY

- NAVREF supports the ACT for Veterans initiative and ORD's priority efforts to enhance access to clinical trials for Veterans;
- NAVREF supports centralization of VA privacy and information security reviews of research protocols to enhance efficiency, increase predictability, and reduce timelines;
- NAVREF supports VA's ability to allow use of commercial IRBs, especially for multi-site industry-sponsored trials already using an accredited commercial IRB.

Thank you again for your attention to these matters. We greatly appreciate your continuing support of the VA research program and your support of the VA-affiliated nonprofit corporations. We look forward to working with you to achieve our vision of a nation in which Veterans receive the finest care based on innovative research and education.