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Preparing Your Laboratory for Cellular Therapy Trials

As the number of clinical trials testing regenerative medicine grows, the demand for capable cellular therapy laboratories will too. Learn more on how to prepare your lab.
Navigating Changes and New Challenges

The blood community has, once again, faced new challenges and changes in recent weeks. In early February, the FDA announced a revised Emergency Use Authorization (EUA) for COVID-19 convalescent plasma (CCP). The revised guidelines, developed after a review of scientific data collected since the original EUA was released, allow only for the use of high-titer CCP for the treatment of hospitalized patients with COVID-19.

Blood centers throughout the country have been collecting CCP since last summer and are now making adjustments. As the community navigates these latest changes, AABB is here to help and provide resources. Our Hot Topic Discussion, held a few days after the FDA released the revised EUA, included insight from FDA leaders who provided more information and answered questions about the revised EUA. In addition, AABB updated its CCP Toolkit to provide further guidance for blood collectors. These and other resources remain available on AABB’s website.

February brought additional issues in the form of weather-related challenges. Severe winter weather wreaked havoc in much of the United States and put a strain on the blood supply. AABB, in collaboration with others in the blood community, continues to encourage ongoing blood donations to ensure the stability and adequacy of the blood supply.

Business Leadership

This issue of AABB News is focused on business leadership—an appropriate topic as we deal with new and ongoing challenges, including those associated with the COVID-19 pandemic. As we continue to adjust to our current challenges, maintaining business acumen is essential to ensure we maintain a sufficient blood supply for patients in need.

Our first feature article, beginning on page 6, highlights cyber security. As professionals in the fields of blood and biotherapies, we are accustomed to ensuring the highest levels of safety and quality for blood and cellular products, but protecting our businesses requires ensuring the highest level of cybersecurity too.

As the field continues to expand, many facilities are expanding their operations through clinical trials. A second feature article, beginning on page 12, offers insight on getting labs ready for clinical trials.

Finally, I thank all the members of our community for your heroic work as we continue to advance the field amidst myriad challenges. Please contact me if AABB can help in any way.

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ABB’s National Blood Foundation (NBF) is well-known for its early-career scientific research grants program, which, since its inception in 1983, has awarded more than $11 million to early-career investigators and boosted the careers of more than 200 leaders of the blood and biotherapies community.

But another valuable facet of the NBF is that it helps to foster mentorship and collaboration among previous grant recipients and those who are active in its community. Through various NBF programs and networking events, current and past recipients of NBF grants are able to connect and collaborate, often leading to important projects and advancements.

* AABB News* spoke recently about this aspect of the NBF with two previous recipients of NBF early-career grants, both of whom have remained active within the NBF community: Moritz Stolla, MD, PhD, from Bloodworks Northwest Research Institute; and Karina Yazdanbakhsh, PhD, from the New York Blood Center.

Stolla received an NBF early-career scientific research grant in 2018 for his research project titled “Cold-stored Platelets for the Reversal of Dual Antiplatelet Therapy.” Through his association with the NBF, Stolla has met and developed ties with many other NBF grant recipients. “The NBF is an excellent resource for networking,” Stolla said. “I have met many people through the NBF whose name I had only read in papers or book chapters before. Receiving an NBF award is one of the first milestones for young investigators trying to establish themselves.”

Yazdanbakhsh, who received her grant in 2000 for her research project titled “Recombinant Antigens as Tools for Identification of Alloantibodies in Patients’ Sera,” has been involved with various aspect of the NBF throughout her career, including serving as a mentor and on several committees. In addition, she was inducted into the NBF Hall of Fame in 2016. Yazdanbakhsh said the benefits associated with an NBF grant reach far beyond the financial reward. “My history with the NBF has been invaluable to me,” Yazdanbakhsh said. “Not only has it allowed me to expand my network of professional friends and colleagues, but it has also helped me develop research collaborations, engage and learn firsthand from top experts, and increase my visibility in our research community.”

**Fostering Mentorship and Collaboration**

Both Yazdanbakhsh and Stolla agreed that their involvement in the NBF was instrumental in fostering mentorship and collaboration.

“I have been incredibly fortunate, having been mentored by Dr. Jim AuBuchon [1985 NBF early-career grant recipient] and Dr. Jim Zimring [2004 NBF early-career grant recipient],” said Stolla. “Both are very inspiring transfusion medicine physicians and scientists. Both are also highly collaborative individuals; they lead by example when solving scientific problems through collaboration.”

Yazdanbakhsh agreed that the mentorship fostered through the NBF has been key in helping advance the careers of burgeoning researchers. “The NBF funding offers the supportive infrastructure to help establish mentor-mentee relationships,” she
said. “By focusing on career development, NBF supports, promotes and sanctions mentoring relationships.”

Stolla added that his association with the NBF helped lead to collaboration between two research groups, both of which include NBF alumni. “My group recently started to collaborate with Dr. Bobby Lee [2020 NBF early-career grant recipient] from the University of North Carolina at Chapel Hill,” Stolla said. “Lee’s group has an intriguing mouse model of hemostasis that we will utilize to characterize recovery of platelet function after transfusion in living organisms.”

**Career Benefits**

Many former grant recipients count the relationships formed through the NBF as being as valuable as the early-career financial support. The encouragement and collaboration of other leading researchers in the field can also provide a significant benefit in boosting one’s career.

“One nice added benefit of my early-career grant was that it led to my participation in the NBF grants review committee the following 2 years,” Stolla said. “This has been the first time for me to review grant applications. I appreciate the opportunity to review grants because the emphasis and the process are very different from reviewing manuscripts for journals.”

Yazdanbakhsh agreed the relationships formed through the NBF were key in career development. “I recently have had the pleasure of mentoring two outstanding NBF early-career grant recipients,” she said. “Improvements in the quality of their grant applications over time that has resulted in securing NIH funding has had the most impact on their careers. Including both of these individuals as key scientific contributors on an NIH program project grant helped strengthen the application — which was funded. In this case, the careers of both mentor and mentees were positively impacted!”

Mentorship and collaboration are key to scientific progress and the NBF has been instrumental in cultivating important relationships in transfusion medicine and biotherapies that have contributed to the overall advancement of the field. A donation to the NBF not only helps support the early-career scientific research grant program, but also provides budding scientists access to collaborative learning opportunities. Donate today in honor of a mentor who helped shape your career!