



ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

Visit ABC's Web site at: www.americasblood.org

2020 #27

July 31, 2020

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Please Note: The ABC Newsletter will not be published on August 7th. We will resume regular publication on August 14th. Thank you for your continued interest.

ABC Participates in Administration Convalescent Plasma Roundtable as National Awareness Campaign is Announced

America's Blood Centers Chief Executive Officer Kate Fry, MBA, took part in a COVID-19 convalescent plasma (CCP) roundtable at the American Red Cross National Headquarters in Washington, D.C. The roundtable featured President Trump joining leaders from several government agencies and industry stakeholders discussing progress being made in the collection of CCP to assist COVID-19 patients in need, and served as a launch point for a federally-backed national convalescent plasma awareness [campaign](#) that will feature [PSAs](#) from leaders of several federal agencies. "From the beginning of the pandemic, the Trump Administration has been expanding access to convalescent plasma as a promising investigational treatment," said U.S. Department of Health and Human Services (HHS) Secretary Alex Azar in the news release announcing the campaign. "Americans who have recovered from COVID-19 have a key role to play by donating plasma with antibodies that have the potential to save lives and help beat the virus. All Americans can help spread the word: If you've recovered from COVID-19, you can help join the fight by donating plasma, because the fight is in us."

During the roundtable, President Trump addressed the media and described convalescent plasma and the role it could potentially play in helping COVID-19 patients recover. "I'm delighted to be here to discuss the remarkable progress being made in the development of plasma," said President Trump. "These therapies transfuse powerful antibodies from the blood of recovered patients to help treat those battling the current infection that we all know so well. Plasma is one of the more delicate ways of doing things."

Ms. Fry detailed the efforts of community blood centers to mobilize to respond to the pandemic. "Thank you, Mr. President, for having this important event today. America's Blood Centers is the national trade association for independent community blood centers. Our members are responsible for over 60 percent of the nation's blood supply and have been at the forefront of convalescent plasma collections in the U.S. over the past four months," said Ms. Fry during the roundtable. "We're excited to announce that, today — that as of this week, independent community blood centers have distributed more than 100,000 doses of COVID-19 convalescent plasma to patients in need. Every blood center — small, medium, and large — across the country has mobilized to do their part in this effort. Of course, we are not slowing or stopping down in any kind of way; we are indeed mobilizing to do even more."

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Administration Led CCP Roundtable and National Awareness Campaign Launch (continued from page 1)

U.S. Food and Drug Administration (FDA) Commissioner Stephen Hahn, MD addressed the safety of CCP and ongoing studies into its efficacy. “I want to thank the American Red Cross [and] America[’s] Blood Centers for the collaboration that we’ve had in the development of the convalescent plasma program...A number of clinical trials beyond the expanded access program are taking place. We’re encouraged by the data; we’ve seen that this is a safe treatment...And even if, at the end of the day, convalescent plasma doesn’t turn out to be the treatment we think it might be, remember that your donations still count with America[’s] Blood Centers and the American Red Cross. They can truly save lives.”



American Red Cross CEO Gail McGovern (left) and America’s Blood Centers CEO Kate Fry (right) at the CCP roundtable.

Also, U.S. Surgeon General VADM Jerome Adams, MD, MPH, who has urged individuals to donate blood throughout the pandemic even challenged young donors to commit to donating blood or plasma. “[T]o the young people out there: We’ve got some work to do. The seniors are showing us up. We need everyone to do their part, because we’re all in this together...We are all in this together. Give blood. Give plasma. Save a life. We’ll get through this, America.”

Other roundtable participants included:

- National Institutes of Health (NIH) Director Francis Collins, MD, PhD,
- NIH’s National Institute of Allergy and Infectious Diseases (NIAID) Director Anthony Fauci, MD,
- U.S. Global AIDS Coordinator and U.S. Special Representative for Global Health Diplomacy Deborah Birx, MD,
- American Red Cross Chief Executive Officer Gail McGovern,
- CSL Limited Chief Executive Officer Paul Perreault, and
- LabCorp Chief Executive Officer Adam Schechter.

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ABC advocates for and advances policies that promote the role of independent blood centers in providing life-saving blood products and recognize the continuous need for a safe and robust blood supply. ABC exists to advocate for laws and regulations recognizing the essential role that independent blood centers play in the healthcare system; promote partnerships, policies and programs that increase awareness about the need for blood donation; and serve as a thought-leader in the advancement of evidence-based medical and scientific solutions related to health and safety.

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Administration Led CCP Roundtable and National Awareness Campaign Launch (continued from page 2)

A [recording](#) of the CCP roundtable is available in addition to a [transcript](#) and [fact sheet](#). President Trump also encouraged individuals who have recovered from COVID-19 to donate CCP during his daily [briefing](#). “Today we’re asking [individuals who have recovered from COVID-19] to visit [Coronavirus.gov](#) — [Coronavirus.gov](#) — and volunteer to donate plasma. We need plasma...from those that were infected and successfully recovered, as most people do. Most people do. Plasma is one of the many promising treatments my administration is accelerating.”

(Sources: CCP Roundtable [Recording](#), 7/30/20; CCP Roundtable [Transcript](#), 7/30/20; CCP Roundtable [Fact Sheet](#), 7/30/20; President Trump [Briefing](#), 7/30/20; HHS [News Release](#), 7/30/20) ♦

Convalescent Plasma EUA Decision Looming?

A [report](#) from the *Wall Street Journal* this week states that a decision on whether to designate convalescent plasma with emergency use authorization status could come next week from the U.S. Food and Drug Administration (FDA) according to the article. “The authorization could come as soon as next week, according to the people, though the agency could also decide to delay a decision,” reported the *Wall Street Journal*. “The designation could open the way for faster and wider access to one of the most promising treatments for COVID-19 patients...An FDA emergency-use authorization could cut red tape for the hospitals and allow faster access to the therapy.” The story also mentioned several studies currently underway to examine the efficacy of convalescent plasma as a therapy for ill individuals with COVID-19. “I think the data are pretty clear that using it as early as possible has advantages, and we should explore that possibility,” said William Hartman, MD of the University of Wisconsin who is participating in Mayo’s expanded access study.

(Source: *Wall Street Journal*, [FDA Nears Decision Authorizing Covid-19 Treatment With Convalescent Plasma](#), 7/29/20) ♦

Ruth Sylvester Retires from ABC

America’s Blood Centers’ (ABC) Director of Regulatory Services Ruth Sylvester will officially retire from ABC as of July 31st. Ms. Sylvester’s significant contributions to ABC, its members, and the blood community during her 14-plus year tenure with the organization have been both innumerable and invaluable. She has been instrumental in organizing, strategizing, leading, and mobilizing ABC’s disaster preparedness and response efforts throughout the COVID-19 pandemic, even postponing her initial retirement date of March 31st to continue to provide expertise and guidance to ABC members, staff, and the blood community. Her career in blood banking has spanned more than 30 years of experience in both clinical laboratories and blood banks, specializing in troubleshooting and improving operations. Before joining ABC, Ms. Sylvester served as director of the Armed Service Blood Program and prior to that, chief of the Air Force Blood Program. In her role as ABC’s Director of Regulatory Services, she has assisted ABC members with a variety of issues pertaining to blood center regulations set forth by the U.S. Food and Drug Administration, the Centers for



Ruth Sylvester (left) and Kate Fry (right) pose for a photo during the ABC Awards of Excellence ceremony.

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Ruth Sylvester Retires (continued from page 3)

Medicare & Medicaid Services, AABB, the Nuclear Regulatory Commission, and other standard-setting organizations. “Among Ruth’s greatest contributions to ABC has been her role in medical readiness and disaster preparedness,” said ABC President Mike Parejko at the ABC Annual Meeting in March during the *Awards of Excellence* ceremony, where she received the organization’s William Coenen President’s Award. “We have seen this first-hand as we have watched her lead ABC’s response to COVID-19, assisting members with their local plans, and serving as a liaison to the AABB Interorganizational Task Force for Domestic Disasters and Terrorism.”

Serving as a key strategist during her military career, Ms. Sylvester played an integral role in the Operation Iraqi Freedom blood support plan, directing the Department of Defense Joint Health Agency that manages the global policies for military departments and combatant commands. She was the first Quality Assurance Officer for the Air Force Blood Program, building the quality program from inception following the FDA’s mandate in 1995. Ms. Sylvester continued leading disaster preparedness efforts after joining ABC and participated in the international group of blood pandemic influenza planners who developed plans to ensure the availability of blood world-wide during a pandemic outbreak.

She will always be remembered for her insight, instincts, selflessness, gregarious laugh, and candidness. Ms. Sylvester will be missed at ABC as the association and its members thank her for years of extraordinary service on behalf members, association staff, and the blood community, while congratulating her on the culmination of a remarkable career. 💧

REGULATORY NEWS

The U.S. Department of Health and Human Services Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) will hold an online public meeting August 26th-27th. The committee plans to “discuss recommendations to improve the blood community’s response to future public health emergencies. In order to facilitate this discussion, key stakeholders from across the nation will present on their lessons learned during the latest pandemic. The committee will analyze strengths and weaknesses from the COVID-19 response on the blood community and blood supply.” The Wednesday session is tentatively scheduled to take place from 12:30 – 5:15 p.m. EDT with Thursday tentively being a full day session from 8:00 a.m. – 5:00 p.m. EDT. Additional information including an agenda will be published on the [HHS website](#) when available.

(Source: ACBTSA Meeting [Announcement](#), 7/24/20)

The U.S. Food and Drug Administration [announced](#) this week that a variance has been granted to a licensed source plasma center to waive restrictions on distribution of COVID-19 convalescent plasma from a paid donor before they have been tested twice in six months and the need to hold for 60 calendar days. 54. 21 CFR 640.69(e)&(f) applies to the distribution of “COVID-19 Convalescent Source Plasma units collected by blood establishments licensed to collect Source Plasma for the commercial manufacture of COVID-19 Hyperimmune Globulin (Anti-COVID-19 H-IG)”

(Source: FDA [Announcement](#), 7/28/20) 💧

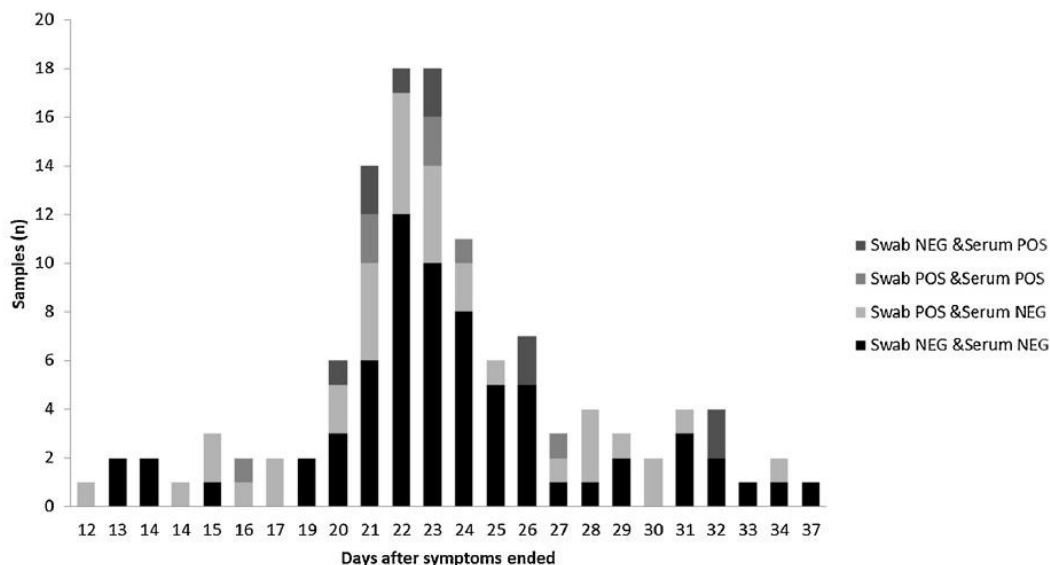
Upcoming ABC Webinars – Don’t Miss Out!

- **ABC SMT Journal Club Webinar** – August 10th from 2 – 3 p.m. (EDT). More details available [here](#).
- **ABC QA Education Webinar** – August 18th from 3 – 4:30 p.m. (EDT). Additional details coming soon.



RESEARCH IN BRIEF

How Long Should a COVID-19 Convalescent Plasma Donor Be Deferred? Researchers in Brazil published results of a study in a “letter to the editor” appearing in *Transfusion and Apheresis Science* that “evaluated a prospective cohort of convalescent COVID-19 patients in order to find potential donors.” Eligibility requirements for participants included “a positive result via a “diagnostic test by nasopharyngeal swab (NOS) reverse transcriptase-polymerase chain reaction (RT-PCR) and resolution of symptoms for at least 14 days. The candidate was then tested for SARS-COV-2 by RT-PCR [by] blood [draw] and NOS.” The authors performed “an analysis of the post-asymptomatic period and the molecular test results [were] carried out...Between April 8th and May 25th, 2020, 119 plasma donor candidates were evaluated” at a single institution. “All have had mild to moderate disease, but none had to be treated as an in-hospital patient.” “[T]he COVID-19 symptomatology lasted from 0 to 33 days. The time period between the end of the symptoms and the blood bank pre-donation screening and sample collection varied from 12 to 37 days.” The researchers discovered that seven individuals (5.8 percent) “had NOS and serum positive tests, 68 (57.2 percent) had both tests negative, 34 (28.6 percent) had only the NOS test positive, and 10 (8.4 percent) had only the serum test positive...Donor candidates with any kind of positive results were excluded for plasma donation. No statistical difference was found between the positive results and the time period without symptoms.” A chart published by the authors “shows the correlation between the days without symptoms and the test results.” Their analysis discovered a “14.3 percent positivity in serum samples (17 [individuals]) and 34.5 percent positivity in NOS (41 individuals), and the latest detected day of each one was respectively on the 32nd and 34th day without symptoms.” The authors concluded that “even considering the low probability of transfusion transmitted SARS-COV-2, and the very few cases analyzed, that blood centers do not collect [convalescent plasma] before the 30th day without symptoms of the donor and if it is done, to have at least the serum tested based on molecular methods.” They advocated that “the precautionary principle might be applied to this situation.”



Courtesy of *Transfusion and Apheresis Science*

Citation: Kutner, J.M., Bonet-Bub, C., Yokoyama, A.P.H., *et al.* Convalescent Plasma for COVID19-How Long Should A Donor Be Excluded from Donation? *Transfusion and Apheresis Science*. 2020: Doi: [10.1016/j.transci.2020.102873](https://doi.org/10.1016/j.transci.2020.102873).

Contributed by Richard Gammon, MD, Medical Director at OneBlood 



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INSIDE ABC

The programs and services described in the Inside ABC section are available to ABC member blood centers and their staff only, unless otherwise specified.

August SMT Journal Club Webinar

The ABC Scientific, Medical, and Technical (SMT) Journal Club Webinar on August 10th at 2 p.m. EDT will feature the articles below:

- [Cost-effectiveness evaluation of the PROPPR trial transfusion protocols](#) (*Transfusion*);
- [A case study of 10 patients administered HBOC-201 in high doses over a prolonged period: outcomes during severe anemia when transfusion is not an option](#) (*Transfusion*); and
- [Is SARS-CoV-2 transfusion transmitted?](#) (*Transfusion*).

Additional details including login information to join the webinar are now available to ABC members.

(Source: [MCN 20-073](#), 7/30/20)

Sign-up Today for the ADRP Digital Marketing Solutions Virtual Master Class

Registration is now open for the upcoming [Digital Marketing Solutions Virtual Master Class](#). This series of three single-day events will occur over the course of three weeks and has been designed to move beyond the basics and build upon the skills needed to excel at your job while providing participants with the latest tools and trends to incorporate into their current business plans.

ADRP has scheduled more than 15 speakers from blood centers of all sizes as well as digital marketing subject-matter experts from Facebook and Google. This will be a hands-on experience, rather than solely lectures, featuring activities designed to engage attendees equipping them with the necessary resources to strategize a plan that can be implemented immediately.

Individuals and teams within the communications, marketing, and public relations departments at your blood centers are encouraged to [register today](#) for the Digital Marketing Solutions Master Class to drive tangible results for both your existing and future digital marketing efforts.





BRIEFLY NOTED

The U.S. Department of Health and Human Services (HHS) Tick-Borne Disease Working Group has announced that it will host its next meeting online via webcast August 13th-14th from 9 a.m. to 5:00 p.m. [Registration](#) is open for the two-day meeting and anyone wishing to make public comments must email their request [here](#) before August 6th. The Tick-Borne Disease Working Group “will review the draft 2020 report to the HHS Secretary and Congress and review and approve graphics and images for the report. The 2020 report will address ongoing tick-borne disease research, including research related to causes, prevention, treatment, surveillance, diagnosis, diagnostics, and interventions for individuals with tick-borne diseases; advances made pursuant to such research; federal activities related to tick-borne diseases; and gaps in tick-borne disease research.” More information including an agenda will be posted on the HHS [website](#) when made publicly available.

AABB has announced a partnership with American Society for Clinical Pathology (ASCP) on a national blood donation awareness campaign. The focus of this initiative will be educating the public on the need for blood donors and connecting them with their local blood centers. “By combining their efforts, AABB and ASCP hope to broaden their reach by amplifying the message across their respective constituencies,” stated the [news release](#). “Members will be encouraged to share this on their social media channels and with family, friends and colleagues. The campaign will also include a patient-facing initiative.”

(Source: AABB [News Release](#), 7/24/20) ♦

WORD IN WASHINGTON

The U.S. Department of Health and Human Services and the American Hospital Association (AHA) [announced](#) a partnership to encourage individuals to donate convalescent plasma. The partnership was announced by the AHA last week as its member hospitals will urge “eligible patients who [have] recover[ed] from COVID-19” to potentially help patients in need by donating.

(Source: AHA [Announcement](#), 7/23/20) ♦

COMPANY NEWS

A [report](#) in *Reuters* states that CoVIg-19 Plasma Alliance will not meet its original goal of beginning clinical trials in July with its hyperimmune globulin therapy candidate. A representative from **Takeda Pharmaceutical**, the company that is leading the coalition of stakeholders, told *Reuters* that [t]he CoVIg-19 Plasma Alliance is ready to start shipping vials to study sites once the trial is approved by regulators in the United States... The National Institutes of Health in the U.S. is the trial sponsor, and is looking at study sites around the world,” according to Takeda.

(Source: *Reuters*, [Takeda-led COVID-19 plasma treatment unlikely to meet July goal of trial start](#), 7/29/20)



We Welcome Your Letters

The *ABC Newsletter* welcomes letters from its readers on any blood-related topic that might be of interest to ABC members. Letters should be kept relatively short and to the point, preferably about a topic that has recently been covered in the *ABC Newsletter*. Letters are subject to editing for brevity and good taste and published after editorial review. Please send letters to the Editor at newsletter@americasblood.org or fax them to (202) 899-2621. Please include your correct title and organization as well as your phone number. The deadline for letters is Wednesday to make it into the next newsletter.



CALENDAR

Note to subscribers: Submissions for a free listing in this calendar (published weekly) are welcome. Send information to newsletter@americasblood.org or by fax to (202) 899-2621. (For a more detailed announcement in the weekly "Meetings" section of the newsletter, please include program information.)

2020

Aug. 13-14. **HHS Tick-borne Disease Working Group Meeting (Virtual)**. More details and registration available [here](#).

Aug. 26-27. **Advisory Committee on Blood and Tissue Safety and Availability Meeting (Virtual)**. More details available [here](#).

Aug. 28-29. **South Central Association of Blood Banks (SCABB) 2020 Annual Meeting & Exhibit Show (Virtual)**. More details and registration available [here](#).

Sept. 9. **10th Annual Symposium Red Cell Genotyping 2020: Visionary Solutions, Bethesda, Md.** More details available [here](#).

Sept. 10. **39th Annual Immunohematology and Blood Transfusion Symposium, Bethesda, Md.** More details available [here](#).

Sept. 16, 23, 30. **ADRP Digital Marketing Solutions Virtual Master Class**. More details available [here](#).

Oct. 3-5. **2020 AABB Annual Meeting (Virtual)**. More information available [here](#).

Oct. 27. **Biomedical Advanced Research and Development Authority (BARDA) Industry Day 2020 (Virtual)**. More information available [here](#).

Nov. 22-24. **2020 ADRP Conference, Phoenix, Ariz.** More details available [here](#).

2021

Mar 8-10. **ABC Annual Meeting, Washington, D.C.** More details coming soon.

June 25-26. **64th Annual California Blood Bank Society Annual Meeting, Santa Clara, Calif.** More details available [here](#).

Sept. 15-17. **4th European Conference on Donor Health and Management, Hamburg, Germany.** More details available [here](#).

CLASSIFIED ADVERTISING

Classified advertisements, including notices of positions available and wanted, are published free of charge for a maximum of three weeks per position per calendar year for ABC institutional members. There are charges for non-members: \$139 per placement for *ABC Newsletter* subscribers and \$279 for non-subscribers. A six (6) percent processing fee will be applied to all credit card payments. Notices ordinarily are limited to 150 words. To place an ad, e-mail: newsletter@americasblood.org

POSITIONS

Executive Director. The International Plasma and Fractionation Association (IPFA) is the international umbrella association supporting the interests and activities of its member organizations involved in the collection of human blood and plasma, and the manufacture and supply of essential medicines derived from human plasma. IPFA is now looking for an Executive Director to exercise leadership and vision by providing strategic direction in

support of its members' contribution to an increased supply of Plasma Derived Medicinal Products (PDMPs) from the not-for-profit sector. The Executive Director will work closely with members of the association to support and promote their interests and contributions to the global supply of PDMPs for patients. The successful candidate will have a track record of demonstrable leadership

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POSITIONS (continued from page 8)

and advocacy in a relevant and/or related field and act as ambassador to the global stakeholder community for the goals and principles underpinning the activities of IPFA and its members. We are looking for a candidate with the following management qualities and competencies: Leadership, Operational planning, Program planning, Human resources planning, Financial planning, Community relations / Advocacy, and Risk management. Further information on the role and activities of IPFA can be found on its website at www.ipfa.nl. Should you be interested in this position and wish to receive the full job description including an overview of the requested qualifications and experience, please contact IPFA at info@ipfa.nl, expressing your interest.

Outside Sales Representative/Event Planner (Fort Smith, Ark.). Account Consultants must develop new partnerships with targeted decision makers in community organizations, educational & religious institutions and businesses to gain support in meeting the needs for volunteer blood donors. Responsibilities include organizing and promoting blood donation events; assessing, developing and implementing strategic/tactical plans to achieve recruitment objective/goals. She/he is expected to develop a customer-focused culture that will result in successful community partnerships and donation awareness. Identify opportunities for growth within current group base and facilitate a plan to achieve growth percentage for total unit collection within territory. Book recurring blood drives for the following year. Develop and maintain relationships with key accounts. Give presentations in order to promote blood collection. Identify and provide feedback on issues regarding customer needs/requirements, customer issues/concerns and satisfaction, competitor activities/strategies, etc. Interact effectively and professionally with team members and all internal/external contacts. Qualifications: Associate/Bachelor's degree preferred, one to three years sales related experience, public speaking/presentation experience preferred, excellent communication skills, and valid driver's license with access to vehicle. Salary Range: Competitive salary, commission plan, and excellent benefits package including health, dental, vision, and life insurance, 401(k), paid time off, and holiday pay. How to apply: <http://arkbi.org/careers/>.

Associate Medical Director. Blood Assurance is seeking an Associate Medical Director to work in our Nashville, TN facility. This position will assist the Medical Director with providing medical and professional guidance to employees of the company and to area medical professionals. Qualified applicants should possess: MD degree required; board certification or eligibility in pathology required (board certification must be secured within 1 year of hire); Transfusion Medicine board certification or eligibility preferred. Must be licensed to practice medicine in the states of our fixed facilities if required by that state (state licensure can be secured after hire). Minimum 5 years prior related experience; blood bank management and cellular therapy experience preferred. Advanced communications skills required, including ability to speak to groups; computer skills and ability to effectively interact with coworkers. Qualified candidates are encouraged to submit an online application at www.bloodassurance.org. Blood Assurance is an EOE and Tobacco Free Workplace.

Chief Medical Officer (Associate Professor, Full Professor). The University of Washington, Department of Laboratory Medicine and Pathology and Bloodworks Northwest is accepting applications for Chief Medical Officer (Associate Professor, Full Professor). This position involves overall responsibilities for providing medical direction and support for all aspects of Bloodworks' activities. The position requires licensure as a physician (M.D. or D.O.) and board certification in Blood Banking/Transfusion Medicine. In lieu of board certification, candidates who meet the requirements for CLIA laboratory director with 3 years' experience in blood collections, immunohematology, apheresis, and cellular therapy will also be considered. University of Washington faculty engage in teaching, research, and service. Please apply at <https://usr57.dayforcehcm.com/CandidatePortal/en-US/bloodworks/>. EO employer – M/F/Vets/ ♡