America's Blood Centers®
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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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Issue #3
January 27, 2017

Update to the Common Rule Protecting Human Research Trial Participants

On January 19, the Department of Health and Human Services (HHS) issued the Final Rule on the "Federal Policy for the Protection of Human Subjects" Common Rule. HHS' 45 CFR 46 safeguards the protection of human subjects in research trials. A number of revisions ABC championed were made to the original 2015 Notice of Proposed Rulemaking (NPRM) from HHS and made it into this Final Rule.

"The major victory for ABC members is the elimination of the provision requiring informed consent for biospecimens, including blood," said ABC CEO Christine Zambricki, DNAP, CRNA, FAAN. "ABC argued vigorously to maintain the current practice that allows research to be performed using previously collected blood samples, without informed consent, as long as the specimens are not linked to an individual."

Here are some of the changes from the 2015 version:

- The final rule rescinds the redefinition of anonymized biospecimens (including left over specimens) as "human subjects" for which informed consent would have been required. This facilitates the continued use of left over specimens from blood centers and blood spots from newborn screening programs for clinical research.
- Multiple references to the yet-to-be developed templates for various documents have been removed citing the inability of the interested public to critically analyze their appropriateness prior to enactment of the rule.
- Standardization of some privacy and security safeguards.
- The NPRM extension of the common rule to all clinical trials at institutions receiving any federal funds (with certain exclusions) was rescinded, recognizing concerns about the provision's ability to address the real gaps in human subject protections being addressed, questions about legal authority, and the complexity the extension would involve.

Some proposed changes in the NPRM that survived in the final rule are:

- Reorganization of informed consent to better assure that a "reasonable person" would be able to understand the risks and benefits of joining a clinical trial.
- Allowance for a broad consent on identifiable biospecimens for use in clinical trials.
- Lowering oversight, e.g. eliminating continuous reviews, for defined "low-risk" clinical trials.
- A requirement for the use of a single ("central") independent review board (IRB) for multisite trials.

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INSIDE:

Our Space:

OUR SPACE

ABC Chief Medical Officer Louis Katz, MD

Avert Your Eyes: Making Sausages, I Mean Policy

The new "Common Rule" for the protection of human research subjects is published and available. The Common Rule governed 15 federal departments and agencies, evolving from the early 1970s and 1980s as the National Research Act. The Department of Health and Human Services' 45 CFR 46 responded to the "Tuskegee Study of Untreated Syphilis in the Negro Male," initiated in 1932, that abused research subjects by neither educating them about the studies they were in, nor providing standard-of-care curative treatments as they became available. It entered the code in its most recent incarnation in 1991. A Notice of Proposed Rule Making was published for comment in September 2015, representing a "wish list" from 16 federal entities (*excluding* the Food and Drug Administration). This first major revision was in response to deaths among contemporary research participants, perceived gaps in the local application of the rule and, critically to me, the changing nature of research, including the proliferation of multisite trials and logarithmic expansion of genomic studies. Among its goals was an extension of protections to subjects in all clinical trials at sites receiving *ANY* federal funding; an enhancement and streamlining of informed consent; and redefinition of even anonymized human biospecimens as "human subjects" to extend to them a requirement for informed consent and tracking.

The last, most controversial, provision was addressed in more than half of the thousands of comments on the rule. It was opposed in 80 percent of those comments. The rationales in its support were an autonomy assertion (vague to my mind) that folks have a right to know what their specimens are being used for, general distrust of the scientific/research enterprise, a desire to know results from testing on these specimens, and to allow subjects to profit from discoveries related to their use. Opposition, including that from ABC, was predicated on several considerations: the feasibility and costs of getting and tracking consent; the waste of valuable research materials; the probability that this requirement would inhibit research; and a paradoxical likelihood that requiring all biospecimens to be traceable would impose greater privacy risks than the current system. Most important to me was the lack of material risk associated with the use of anonymized specimens.

ABC centers have participated in countless studies for years providing anonymized (often left over) blood samples to companies developing and improving supplies we use daily. You may be glad to know, that in the final rule, the classification of biospecimens as "human subjects" and the consent requirement were rescinded. What remains is still controversial (you will have to read the document), but compromise is at the core of a functioning democracy. As such, we got an important part of what we asked. I am certain this will not be the last time rational policy is made in the next several years.

lkatz@americasblood.org

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ABC is an association of not-for-profit, independent community blood centers that helps its members provide excellence in transfusion medicine and related health services. ABC provides leadership in donor advocacy, education, national policy, quality, and safety; and in finding efficiencies for the benefit of donors, patients, and healthcare facilities by encouraging collaboration among blood organizations and by acting as a forum for sharing information and best practices.

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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.

Top 10 Reasons to Attend the ABC Annual Meeting

Besides getting to enjoy the company of the outstanding ABC staff members, there are a myriad of reasons for attending the 55th Annual ABC Meeting at the Ritz-Carlton (Pentagon City) hotel in Arlington, Va., this March.

1. The Annual Meeting is an opportunity for some of the brightest minds in the blood industry to share knowledge and exchange ideas.

2. The cherry blossoms are predicted to be in full bloom that week and are a sight you don't want to miss.

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INSIDE ABC (continued from page 3)

3. Dress up in your finest and enjoy the delicious FABC reception fare at the famous Hay-Adams hotel with breathtaking views.

4. The Annual Meeting is also a chance to unwind and network with other professionals in the industry.

5. The 55th Annual Meeting offers more CME credits than ever before!

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INSIDE ABC (continued from page 4)

6. Spend some time enjoying the numerous historical and tourist attractions.

7. The meeting will be held at the Ritz-Carlton (Pentagon City) hotel. This hotel is not only considered one of the finest hotels in the area, but also one of the most refined—even the servers must take etiquette classes before they are allowed to serve patrons.

8. D.C. was named the "Restaurant City of the Year" for 2016 by Bon Appétit magazine. You will find an enormous variety of eclectic and delectable eateries within walking distance and downtown.

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INSIDE ABC (continued from page 5)

9. Don't miss the positively gratifying FABC *Awards of Excellence* and entertaining Talent Show.

10. Cap off this trip by joining blood center leaders from across the country on Advocacy Day to promote key industry issues and concerns to lawmakers.

Whatever your reason(s) for joining us at the ABC Annual Meeting, we look forward to seeing you there! To register for the meeting, email Lori Beaston.

GLOBAL HEALING

Improving Access to Safe Blood: The International Blood Safety Forum

Kicking off the weekend of the ABC Annual Meeting is the International Blood Safety Forum on March 24 at the Ritz-Carlton. The forum is co-hosted by Global Healing and ABC, with sponsorship from Helmer Scientific and Cerus Corporation. President of AABB and keynote speaker Zbigniew (Ziggy) M. Szczepiorkowski, MD, PhD, FCAP, will discuss the future prospects for expanding access to affordable safe blood in developing countries, the potential impact on Sustainable Development Goals for maternal and child mortality, as well as access to essential medicines.

For a full agenda on the forum and list of speakers, visit the Global Healing website and register today!

UPDATE TO THE COMMON RULE (continued from page 1)

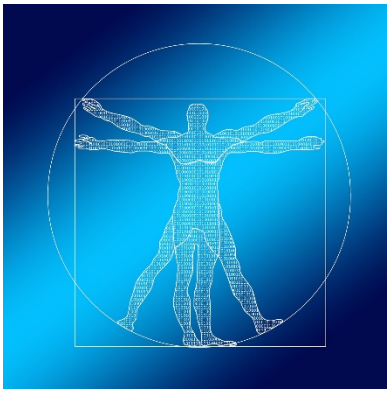
The Common Rule development began in the 1970s with the recognition of the abuses perpetrated in the "Tuskegee Study of Untreated Syphilis in the Negro Male." The original rule was published in the CFR in 1992. Efforts to update the rule to reflect recent developments in clinical trial design and technologic advances were initiated in 2011. In 2015, HHS and 15 other federal government entities (excluding the FDA, which has its own rules) published the NPRM and left it open for comments. More than 2,100 comments were received.

"The ability to use unidentified samples without specific consent is important in medical research and this need was recognized in the Final Rule," said ABC President and Gulf Coast Regional Blood Center Chief Medical Officer Susan Rossmann, MD, PhD. "We are making our way into the new realm of individual information, in the biospecimen area, as well as other areas of life. And we are struggling to define the limits of individual control. The final rule makes a clearer move in this direction. The rule, however, only begins to address the problem of administering a consent that is truly understood by research participants."

There are two major issues this Final Rule will have to face moving forward. The first one is the bipartisan "Cures Act" signed by President Obama just before leaving office. The Cures Act allows for less paperwork and fewer administrative burdens from FDA regulations. It also calls on HHS and the FDA to collaborate "to the extent practicable and consistent with other statutory provisions" any differences in the human subject regulations between the Common Rule and FDA's regulations. The government has three years to complete this process with a mandatory progress report due after two years.

The other major issue is the Congressional Review Act, which allows Congress 60 legislative days to dismantle regulations after any ruling goes into effect. Because this ruling was issued under President Obama, there is speculation that it may be revamped under the new Administration. President Trump has not mentioned a stance on clinical trials or research so far.

Retaining the Donor, One Click at a Time



Retaining and recruiting blood donors remains a challenge. While 6.8 million blood donors come every year to blood centers across the country to give blood, only a handful will return, according to the AABB 2013 survey report. On average, a whole blood or red blood cell donor will only return 1.6 times in 12 months to donate blood again. Apheresis platelet and plasma donors are, on average, more loyal, however, a large amount of that population will soon age out (see our *Newsletter #31*, 2016).

Donor recruitment and retention professionals, along with collections teams, rely on their donor management system (DMS) for a number of aspects: scheduling appointments, having a patient schedule their own appointments, donor eligibility, etc.

"Donor Management Systems are becoming more sophisticated, and donor recruitment professionals are asking them to be that way so we can perform more targeted donor recruitment," said Amanda Hess, director of donor relations at Mississippi Valley Regional Blood Center (MVRBC). "We need better information in these blood establishment computer systems (BECS) and modules to better target the donors and customize how we recruit and contact them."

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RETAINING THE DONOR (continued from page 7)

While some systems include a variety of features like a customized smartphone app and two-way texting, other DMSes offer less functionality and do not offer much more than a few pieces of basic contact information. Of course, the price-points are very different and with blood center budgets tightening, blood center CEOs and IT directors have a lot to consider when thinking about investing in a feature-rich DMS. But this last year was especially tough for many blood centers who experienced longer, and more pronounced, periods of low inventory levels than in previous years, according to information garnered by ABC from our member centers.

"It would be very helpful to have which method the donor prefers to be contacted by, as phone calls become less and less effective," said Ms. Hess. "For every hour of calling, only two donors will pick up the phone and speak with us."

Other factors inhibiting implementation of a full-featured DMS are time and resources. In order to update or implement a DMS, organizations need extra IT staff to configure the software or hire people outside their organization to remain in compliance with continuously changing regulations.

"When the universal Zika testing guidance came out, we needed to work with our internal teams and our BECS vendor (IT Synergistics) to have everything from the label requirements to the donor questionnaire updated," said Jennifer White, manager of Information Systems at MVRBC. "Our systems presented much of the flexibility that was needed to implement. The label requirements were very specific and thanks to our vendor relationship with partial center ownership, IT Synergistics was able to utilize a well-established process for development. The development involved designated center SMEs and a quick release to centers was supported."

As more blood centers merge to form these multi-armed organizations, the more challenging compliance-driven updates can become. That's part of the reason why MAK-SYSTEM, an international provider of blood center software, has everything configurable without needing to go to a vendor, said Alexandre Kiskovski, product manager vice president at MAK-SYSTEM.

Ms. White said her team did configure her organization's DMS and BECS after the final rule was passed in May 2015—and she said it was a much faster and preferable process than working with their vendor; however, she is looking forward to the day when her team can easily download a required update, e.g. those to comply with FDA guidance, online.

Still another avenue toward a fully-featured DMS is to create your own. San Diego Blood Bank (SDBB) launched MySDBB in 2011. The program took the IT department at her center three years to create, but is now totally customized to their blood center and interfaces seamlessly with their BECS and app—MySDBB. Donors can make appointments, check their hemoglobin levels, and even their cholesterol. For the donor it's a "mini wellness site," said Leslie Eagan, manager of partner relations at SDBB. For the blood center it is a full-featured software system.

"It's great because it has all the attributes I need, let's say I only want to talk to O-negative eligible donors with a visit within the last two years, male, live near a certain location—I can dial it down or if I want to do a mass ad-hoc email with no specific criteria, just who is eligible, I can do that too," she added. A new version with more custom features, such as automated inventory control, labeled RedConnect, will replace MySDBB later this year and will be for sale to other centers as well.

As an in-house developed DMS, there was no worry at SDBB about having to insure integration and connectivity with their BECS system, something IT departments with more segmented and modular systems

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RETAINING THE DONOR (continued from page 8)

have to worry about. Some software companies, like MAK-SYSTEM, took note of this trend years ago and integrated full-feature DMSes into their BECS system.

"Our customers like our system because they control the entire supply chain. They can call to recruit donors, ship the product, even track hemovigilance, all from one system. Our Donor Management Systems are just one part of the system," said Mr. Kiskovski, who added their customers decide in a forum what the next update to their system will be and every six months those features are added as updates.

For the future, blood centers' IT and donor relations professionals are keeping their eyes on these kinds of all-inclusive systems with easy-to-update abilities that work seamlessly with their BECS and can target donors as precisely as their genotype.

RESEARCH IN BRIEF

First case of Variant Creutzfeldt-Jakob disease (vCJD) diagnosed in prion protein codon 129 methionine-valine (MV) heterozyogote. A man in the U.K.died and an autopsy was performed with vCJD confirmed at postmortem. All prior cases were methionine homozygous (MM). This was not unexpected as heterozygotes with long incubation periods have been described with other prion diseases. The authors stated it remains uncertain as to whether this case marks the start of a second wave of vCJD in people from the U.K.

Citation: Mok T., Jaunmuktane Z., Joiner S., *et al*. Variant Creutzfeldt–Jakob Disease in a Patient with Heterozygosity at *PRNP* Codon 129. *New England Journal of Medicine*. January 19, 2017. DOI: 10.1056/NEJMc1610003.

Filtered xenon flash light (fXe treatment) inactivated bacteria in apheresis platelet concentrates in plasma. fXe treatment is ultraviolet C (UVC) light pulsed from an Xe flash lamp. The bacteria *Staphylococcus aureus* and *Streptococcus dysgalactiae* were inactivated without regrowth in PLT concentrates stored for six days. In vitro functional characteristics of the platelets were not significantly affected.

Citation: Abe H., Shiba M., Niibe Y., *et al*. Pulsed xenon flash treatment inactivates bacteria in apheresis platelet concentrates while preserving in vitro quality and functionality. *Transfusion*. January 12, 2017. DOI: 10.1111/trf.13984.

Buffy coat-derived granulocytes could be an alternative to apheresis granulocytes collected from stimulated donors. Granulocytes have been looked at as an alternative to apheresis products from donors pretreated with dexamethasone and granulocyte colony-stimulating factor. The latter are time-consuming to prepare and so are not optimal for the treatment of neutropenic, septic patients needing immediate intervention. This study pooled 10 buffy coats that then showed adhesion, chemotaxis, reactive oxygen species production, degranulation, NETosis and *in vitro* killing of relevant potential pathogens. The authors conclude that basic granulocyte functions were well preserved *in vitro* and that using them might relieve concerns about growth factors, corticosteroids, and the use of hydroxyethyl starch seen in apheresis granulocytes from stimulated donors.

Citation: van de Geer A., Gazendam R.P., Tool A.T.J., *et al*. Characterization of buffy coat-derived granulocytes for clinical use: a comparison with granulocyte colony-stimulating factor/dexamethasone-pretreated donor-derived products. *Vox Sanguinis*. January 25, 2017 online. DOI: 10.1111/vox.12481.

BRIEFLY NOTED

A type II diabetes medication, metformin, to be studied in the fight against sickle cell disease (SCD). Researchers at Baylor College of Medicine and Texas Children's Cancer and Hematology Centers discovered a gene, FOX03, which seems to modulate the production of fetal hemoglobin (HbF). Both SCD and beta-thalassemia patients have improved clinical status associated with increased HbF levels. Four hundred patient blood samples were evaluated with whole exome sequencing and mutations in FOX03 were associated with the amount of HbF produced. Previous research has associated the metformin with stimulation of FOX03. A clinical trial, with funding from Pfizer, has launched to study the effectiveness of metformin in patients with SCD and thalassemia-b. (Source: Baylor College of Medicine press release, January 10, 2017).

The World Health Organization's (WHO) executive board meeting commenced on Monday, January 23, 2017 in Geneva, Switzerland. This two-day meeting of 34-member health professionals will draw up a short list of five candidates for the new director-general position. The board will then interview them and eliminate two, leaving three up for vote at the World Health Assembly in May 2017. Also on the agenda is to discuss the need for a global consensus on blood donation guidelines and the WHO's response to significant health emergencies as well as the threat of polio, antimicrobial resistance, and issues regarding migrant health. (Source: WHO website)

Researchers are presenting maternal safety toolkits at the Maternal-Fetal Medicine's annual meeting on Friday, January 27. The toolkits are designed to reduce complications from obstetric hemorrhage, severe hypertension, and early elective delivery—the leading causes of maternal morbidity and mortality. Researchers with the California Maternal Quality Care Collaborative, based at Stanford University, Palo Alto, Calif., will speak on the 21 percent reduction in severe hemorrhages they found in their 99 hospital-based study in California. (Source: *ScienceDaily*, Reduction of the most common cause of maternal death worldwide. January 23, 2017)

Female physicians provide better outcomes for patients, but are paid less. A September 2016 study showed there was an 8 percent pay discrepancy between female and male academic physicians (Jena, *et al*). In a new study, researchers found not only are female physicians being paid less than their male counterparts, but their patients are faring better. The researchers examined data from hospitalized Medicare patients, with a myriad of conditions, and found those patients who saw a female internist had a lower 30-day readmission rate, and a lower 30-day mortality rate than those patients who saw a male internist. An accompanying editorial noted that in a system that promotes pay for performance, women are not being treated with equity. "Such equity promises to result in better professional fulfillment for all physicians as well as improved patient satisfaction and outcomes," noted the commentators.

Citations: Jena A.B., Olenski A.R., Blumenthal D.M. Sex differences in physician salary in US public medical schools. *JAMA Internal Medicine.* September 2016. DOI: 10.1001/jamainternmed.2016.3284.

Parks A.L. and Redberg R.F. Women in Medicine and Patient Outcomes: Equal Rights for Better Work? *JAMA Internal Medicine*. December 16, 2016 online. DOI: 10.1001/jamainternmed.2016.7883.

Tsugawa Y., Jena A.B., Figueroa J.F., *et al*. Comparison of hospital mortality and readmission rates for Medicare patients treated by male vs female physicians. *JAMA Internal Medicine.* December 19, 2016. DOI:10.1001/jamainternmed.2016.7875.

The Commissioner of the Food and Drug Administration (FDA) describes risk-benefit approach of the agency. Robert Califf, MD, discussed the pressures at the agency to expedite FDA approvals. Dr. Califf recalled the historical tragedies in therapeutic development that were caused by erroneous

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BRIEFLY NOTED (continued from page 10)

assumptions, and made the case for unbiased expert evaluation of drugs and devices using high quality data sets. He described the benefit-risk frameworks used at the agency—one for medical devices required to have premarket approval, and the other for human drugs and biologics. He highlighted the need for an agency-wide understanding of how to operate within these frameworks and why they are important. Dr. Califf expressed his desire that future leadership continue to balance the need for innovation and development with safety and effectiveness.

Citation: Califf R. Benefit-Risk Assessments at the US Food and Drug Administration. JAMA. January 20, 2017. DOI: 10.1001/jama.2017.0410.

REGULATORY NEWS

The Center for Biologics Evaluation and Research (CBER) published its guidance agenda for 2017. Of particular relevance to blood centers are the final guidance on "Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion"; a draft guidance on "Implementation of Pathogen-Reduction Measures to Reduce the Risks of Transfusion-Transmissible Infections in Transfused Platelets and Plasma"; and a draft guidance on "Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Products." While CBER plans to develop guidance documents on these topics, they did make clear they are not bound by the list. Guidances related to transfusion-transmitted babesiosis and to allow greater flexibility on the use of plasma products for transfusion or further manufacture are not on the 2017 agenda.

The International Council for Commonality in Blood Bank Automation (ICCBBA) is seeking input on a document. The ICCBBA seeks input on their document "Internationally Standardized Terminology for Regenerated Tissue and Seeded Scaffolds." It proposes terminology and attribute groups in regards to regenerated tissue. They are asking commenters if additional class names and/or attributes should be added and if so, what are they? To comment on the document, you can either email or fill out the online form. Responses are due by January 31, 2017.

PEOPLE

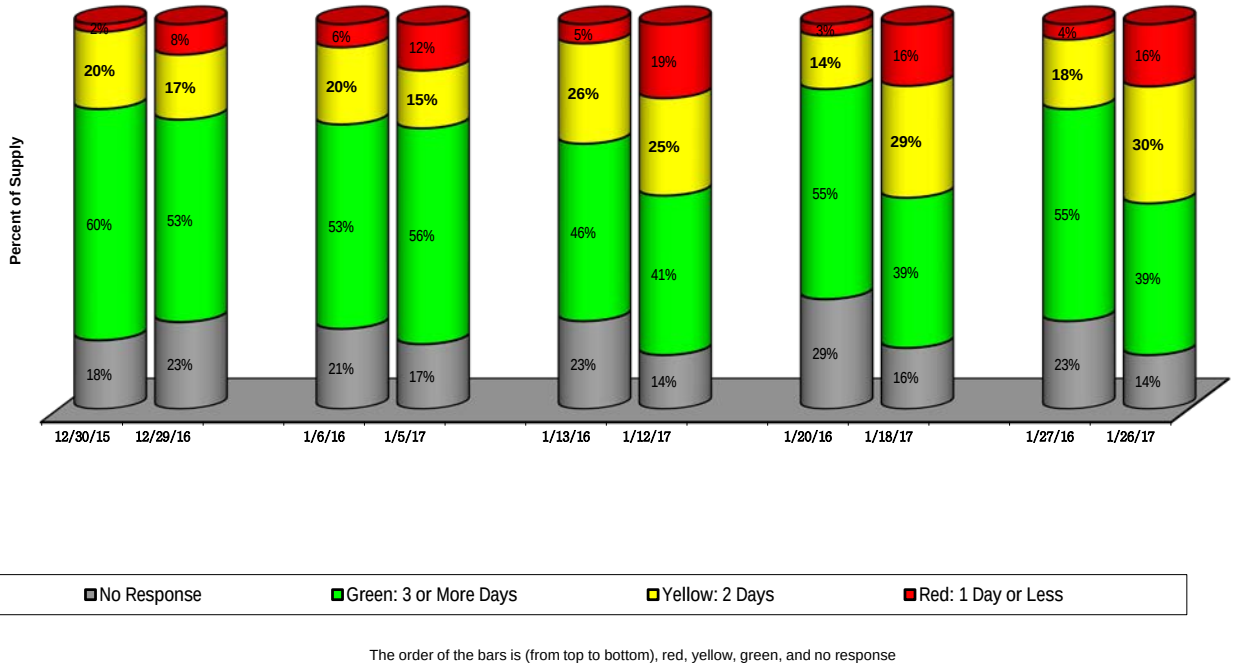
National Institutes of Health (NIH) Director Francis Collins, MD, to stay. Last week, President Donald Trump asked Dr. Collins, who has headed NIH for eight years, to stay. For how long, however, is unclear. "We just learned that Dr. Collins has been held over by the Trump administration," an NIH spokesperson said in a statement to *Science*. "We have no additional details at this time." Other people being considered for the position, including U.S. Representative Andy Harris (R-Md.). (Source: *Science Magazine*, Trump asks NIH Director Francis Collins to stay on. January 19, 2017)

ABC Webinar
"9 Ways to Energize, Empower and Engage Your Employees"
February 7, 2017
2 p.m. EST

As presented by Gary Markle, founder of consulting firm Energage. Register for the webinar here.

Send your talent-filled videos to Jodi Zand to enter into the ABC's Got Talent Season II!

STOPLIGHT®: Status of the ABC Blood Supply, 2016 vs. 2017



The order of the bars is (from top to bottom), red, yellow, green, and no response

Facebook Live Creates New Avenues for Blood Centers to Communicate with Blood Donors

OneBlood, the not-for-profit blood center serving most of Florida and parts of Georgia, Alabama, and South Carolina, is using live social media capabilities on a regular basis and as a result, the blood center is experiencing increased engagement with its content.

"Social media has always been a powerful tool to speak directly with our audience. With the introduction of Facebook Live the ability to instantaneously communicate with your viewers in real-time and share important information with them live takes communicating to a new level," said Susan Forbes, Vice President of Marketing and Communications for OneBlood. Read more on ADRP's blog.

Early Bird Sponsorship Package Opportunities

Valued sponsors, don't miss your opportunity to register for early bird sponsorship packages! The deadline for early bird sponsorship pricing is **Jan. 31.** This discounted rate is available to any organization sponsoring two or more ABC meetings/workshops for calendar year 2017. Sponsoring an ABC meeting allows vendors to increase visibility among their customers and to network with key blood center decision-makers. Contact Jodi Zand for more details.

MEMBER NEWS

The San Diego Blood Bank (SDBB) donated a blood mobile to the State Center for Blood Transfusions in Yucatan, Mexico. No longer compliant with the new pollution standards set by the State of California, this blood mobile will help save lives by improving the availability and safety of blood supply in Mexico. Global Blood Fund helped to arrange the donation, which took place on January 23. The bloodmobile is expected to arrive in Mexico sometime next month. SDBB has already replaced this vehicle with a new bloodmobile, purchased through a donation from the Walter J. and Betty C. Zable Foundation. "We're so happy to extend the life saving mission of one of our bloodmobiles, and assist in filling a dire need for blood collection in the Yucatan" said SDBB's CEO, David Wellis. (Source: SDBB press office)

Rep. Pete Aguilar stopped in at LifeStream in San Bernardino, Calif., on the Martin Luther King, Jr. holiday to donate blood. Community groups volunteered to staff tables at various LifeStream locations that day to greet blood donors in honor of Dr. King's memory and his call of service toward others. "I'm glad I was able to spend Martin Luther King Jr. Day volunteering in my community," said Rep. Aguilar. "It's important to me to honor Dr. King's legacy through service in my region, and I'm grateful to LifeStream for helping me make that possible. Donating blood is a simple but significant way to make a difference." (Source: LifeStream press office)

GLOBAL NEWS

Countries vying to house E.U. health watchdog agency. Even before England begins to prepare for their exit from the E.U., a number of European countries are voicing their desire to house the European Medicines Agency (EMA). The London-based EMA is a health agency watchdog group that employs about 900 people and has an annual budget of €300 million ($322.5 million). As of the time of this article, the governments of Netherlands, Ireland, Italy, Sweden, Austria, Hungary, and Malta all announced they will try to house the EMA after Brexit. Spain, Denmark, Germany, and Finland have all unofficially expressed an interest as well. (Source: *Science Magazine*, At least seven countries are jockeying to host EU's medicine watchdog after United Kingdom leaves. January 20, 2017)

COMPANY NEWS

Bio-Rad Laboratories, Inc., to buy droplet-testing company. Bio-Rad Laboratories, a Billerica, Mass.,-based research and clinical diagnostic producer, announced it has reached a definitive agreement to purchase RainDance Technologies, Inc., a droplet-testing provider. The terms of the acquisition were not disclosed, but the acquisition is expected to take place during the first quarter of 2017. The announcement comes days before 10X Genomics won in a proceeding against RainDance to invalidate one of its patents. (Sources: Bio-Rad press release, January 16, 2017; 10x Genomics press release, January 20, 2017)

CALENDAR

2017

Feb. 8-9. **FDA Public Workshop: Identification and Characterization of the Infectious Disease Risks of Human Cells, Tissues, and Cellular and Tissue-Based Products, College Park, Md.** For more information, click here.

Feb. 13-14. **AABB U.S. Hemovigilance Symposium, Atlanta, Ga.** Click to register and for more information.

February 13-15. **Pharma Conference: 13th Annual FDA and the Changing Paradigm for HCT/P Regulation, Alexandria, Va.** For more information, click here.

Mar. 2-3. **IPFA 2nd Asia Workshop on Plasma Quality and Supply, Yogyakarta, Indonesia.** To register for the workshop, click here.

Mar. 24-28. **Annual Meeting, America's Blood Centers, Washington, D.C.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

Mar. 25. **Board Meeting, America's Blood Centers, Washington, D.C.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

April 6. **FDA Public Workshop: Emerging Tick-Borne Diseases and Blood Safety, Bethesda, Md.** For more information, click here.

Apr. 18-19. **Heart of America Association of Blood Banks (HAABB) 50th Annual Spring Meeting, Kansas City, MO.** For more information and to register, go to http://www.haabb.org.

May 1-3. **ADRP 2017 Annual Conference, Chicago, Ill.** More information is available on the website.

May 16-17. **IPFA/PEI 24th International Workshop on "Surveillance and Screening of Blood-borne Pathogens", Zagreb, Croatia.** To register, click here.

May 17-19. **Cellular Therapies and Transfusion Medicine in Trauma and Critical Care-Looking Towards the Future, San Francisco, Calif.** Presented by Blood Systems, Blood Systems Research Institute, and the University of California San Francisco. For more information, or to register, click here.

June 6-8. **Technical & Quality Workshops, America's Blood Centers, Omaha, Neb.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

June 17-21. **27th Regional Congress of the ISBT, Copenhagen, Denmark.** Click here to register for the event.

Aug. 1-4. **Summer Meeting, MD Workshop & Golf Tournament, America's Blood Centers, Providence, R.I.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

Aug. 4. **Board Meeting, America's Blood Centers, Providence, R.I.** Contact: ABC Meetings Dept. Phone: (202) 654-2901; e-mail: meetings@americasblood.org.

Sept. 11-12. **IPFA/BCA 3rd Global Symposium on The Future for Blood and Plasma Donations, Atlanta, Ga.** Registration will open in mid-September.

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, contact Leslie Maundy at the ABC office. Phone: (202) 654-2917; fax: (202) 393-1282; e-mail: lmaundy@americasblood.org.

POSITIONS

Reference Laboratory Supervisor (Full Time). Blood Bank of Hawaii is seeking a successful leader to oversee and coordinate all reference lab work and product quality control testing services. We are a nonprofit, community-based organization that provides blood components and clinical/technical services to hospitals, physicians and patients throughout Hawaii. The ideal candidate will encompass a high standard for accuracy, follow-up and follow-through, and thrive in an environment where problem solving is a necessity. Will work with team members ensuring compliance at all times, and will also be responsible for the administrative/supervisory functions offering support and guidance to personnel. The incumbent will also serve as a technical resource to hospitals and other departments outside their primary responsibility. If you are up for the challenge, we want to talk to you! Minimum qualifications include baccalaureate degree in Medical Technology or in a related science from an accredited college or university; Certified Medical Technologist by ASCP; eligible for Clinical Laboratory Technologist license by the Department of Health of the State of Hawaii. Previous work experience as an MT in hematology and immunohematology is preferred; certification as a Specialist in Blood Banking (SBB) is highly desirable. Complete an online application by visiting www.BBH.org.

Chief Medical Officer. Traditional blood banking is at an exciting inflection point, needing to respond to a number of local and national market changes. The San Diego Blood Bank (SDBB) is in a unique position to be one of the leaders of the blood industry into the future, by leveraging and extending its competencies to have even greater impact in our community's health. SDBB will continue our mission of providing high quality and blood and biological products on a local, regional and national scale while simultaneously integrating into local and national scientific and clinical communities to actively drive the future of healthcare through research. The San Diego Blood Bank is now searching for a Chief Medical Officer (CMO) to provide medical oversight of our opportunities in blood banking and in life science research and clinical trials, including the Precision Medicine Initiative. The CMO will help drive SDBB's efforts to position itself as a visionary leader in both its traditional blood banking market as well as in emerging life science markets. Education: M.D. or D.O. degree, with subspecialty board certification in hematology or transfusion medicine preferred. Certifications/Licenses: Active, unrestricted California medical license. San Diego Blood Bank is an Equal Opportunity Employer. EEO/Minority/Female/Disability/Vets. sandiegoblood-bank.applicantpro.com

Executive Director of Quality Assurance (Shreveport, LA). LifeShare Blood Centers is currently looking for an Executive Director of Quality Assurance, whose primary responsibility is to develop a system that ensures that policies and procedures regarding the manufacturing processes of the blood center operation are in compliance with standards and regulations governing the blood banking industry as well as providing leadership of the staff working in the quality department. The Executive Director will oversee the activities of the QACs, reviewing reports and trends to determine errors in procedure(s) or training. The ECQA implements and achieves the quality/compliance goals and objectives of the organization. B.S. in Medical Technology or related field required. Must be familiar with FDA regulations governing blood banking, AABB standards and must have significant work experience managing quality programs and procedures in a blood bank or hospital laboratory environment. To apply, please visit: www.lifeshare.org under the careers tab.

Director of Collections (Minnesota Division). (Reports to: Vice President Donor Services; Status: Full-Time, 1.0FTE, and Exempt; Benefits: Medical, Dental, Vision, 401K, Life Insurance, PTO and EST and more) Directs all blood collections operations for the Minnesota donor centers and mobile operations. Provides guidance and oversight to the team that embodies the Innovative Blood Resources (IBR) mission and values and promotes successful collections processes/outcomes. Ensures collections operations and mobiles are run in a manner that results in safe and compliant blood products and services that consistently delights donors and sponsors. Ensures a working environment for the Minnesota Collections leaders and team that is supportive and productive through recognition, feedback, coaching and development. Responsible for collections team, collections support functions and vans/mobiles drivers. Provides guidance to collections leadership in budget development, staffing models, performance reviews, goal development and goal development and achievement. Works collaboratively with the Manager of Donor Recruitment, Manager of CMC, Manager of Collections Quality and Director of Donor Services in Nebraska.

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POSITIONS (continued from page 16)

To apply please go directly to our website with an updated resume.

Center Manager (Beaumont, Texas). LifeShare Blood Centers is currently seeking an individual to fill a key leadership position within our organization. The Center Manager is accountable for operational objectives and will ensure strategic plan is met. The position tracks and trends key performance indicators, quality metrics and financials and takes appropriate action to ensure the business viability. Bachelor's degree in Applied Sciences or Business required with MBA preferred. Demonstrated success of execution of strategic objectives in challenging and highly regulated environment. Ten years of progressive managerial experience required with experience managing donor recruitment and donor services a plus. LifeShare has been a part of the community since 1942, providing local hospitals and our employees with great benefits. To apply, please visit: www.lifeshare.org under the careers tab.

Medical Technologist (Shreveport, LA). LifeShare Blood Centers is currently looking for a Medical Technologist in our Reference Lab. The Med Tech performs complex antibody workups and compatibility testing of donor and patient blood samples, recording observed results, making interpretations, completing reports and paperwork required to charge accounts for testing. The Med Tech performs special serological tests to define immunohematological problems and coordinates investigations with LifeShare's molecular testing laboratory and communicates findings with requesting facility to assist with the determination of appropriate transfusion therapy. Bachelor's degree in Medical Technology or related science field required. MT(ASCP) or MLS(ASCP) or equivalent national accrediting organization required. Current CLS licensure or license eligible. Two to three year's blood banking experience. To apply, please visit: www.lifeshare.org under the careers tab.

President/CEO. Central California Blood Center is a successful growth oriented, independent, not-for profit organization serving hospitals in the Central San Joaquin Valley in California seeking a President/CEO. The successful candidate will have demonstrated leadership experience and must possess exceptional strategic planning abilities coupled with strong interpersonal skills to maintain and cultivate supportive relationships within the regional health care sector and the community and beyond. This executive leadership position is accountable for operational objectives providing leadership and direction to the organization in alignment with Board of Directors to ensure strategic plan is met to execute our mission, vision and core values. Demonstrable success building teams to drive operational success in challenging and highly regulated environments required. Candidates ten years progressive managerial experience and baccalaureate degree required with an MHA, MBA a plus. EOE/M/F/Vet/Disabled. Please submit resume with salary history to deller@donateblood.org or mail to Dean Eller, Central California Blood Center, 4343 W. Herndon, Fresno, CA, 93722.

Reference Technologist III (Job 08030 Seattle (First Hill); Immunohematology Reference Laboratory). Bloodworks Northwest is currently seeking an experienced Medical Laboratory Technologist/Blood Bank Technologist to work in the Immunohematology Reference Laboratory (IRL) at our First Hill Seattle location. This position is eligible for sign on bonus and also offers great benefits and competitive pay. Requirements include: Bachelor of Science degree in clinical laboratory science or other biological science or equivalent; education must meet CMS/CLIA qualification requirements to perform high complexity testing. Also required are two years of immunohematology reference laboratory experience and current certification as MLS (ASCP), BB (ASCP) or MLT (ASCP) or equivalent certification. SBB(ASCP) certification is preferred. The requirement for two years of Immunohematology reference lab experience may be waived with SBB(ASCP) certification. Demonstrated familiarity with computers and keyboarding skills for performing order entry, and the ability to see red, green, blue and yellow are required. We are also looking for excellent customer service skills and the ability to prioritize and reprioritize, and handle tight deadlines, stressful situations and emergency requests. IMPORTANT NOTICE REGARDING APPLYING: Please visit our website at www.bloodworksnw.org and apply to either jobs 08029 or 08030. EEO Employer

Clinical Laboratory Scientist. Located in the heart of the magnificent coastal redwoods of Northern California, The Northern California Community Blood Bank is a nonprofit blood bank serving Humboldt and Del Norte Counties. The Northern California Community Blood Bank has an immediate opening for a Clinical Laboratory Scientist. The Clinical Laboratory Scientist is responsible for activities related to processing, testing, storage, transportation, and other handling of blood and blood products. The Clinical Laboratory Scientist performs reference immunohematological testing and participates in training, validation, implementation of new procedures, and compliance with regulatory and standard-setting agencies. Experience, Education and Licensure: Four-year degree from an accredited college or university in science, medical technology or a related field. Valid current California license as a Clinical Laboratory Scientist. Preferred experience as a technologist in a clinical laboratory and familiarity with standard laboratory methods and techniques, ability to perform standardized routine testing, specialized testing in blood donor processing, and immunohematology. Will train the right candidate. To Apply: Contact Adam Summers (asummers@nccbb.org); Northern California Community Blood Bank; 2524 Harrison Avenue, Eureka, CA 95501; (707) 443-8004.

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POSITIONS (continued from page 17)

Associate Medical Director. Michigan Blood seeks Physician, board certified in Clinical Pathology or Hematology and board certified in Transfusion Medicine (or eligible to achieve certification in the first year of employment), to assist in all medical/clinical aspects of donor eligibility, therapeutic apheresis, transfusion medicine consultation and patient reporting from our clinical laboratories. Candidate will also assist with the medical and technical review of SOP's, validations and variances as assigned. Requirements include being a team player with excellent verbal and written communication skills. Experience in donor qualification, therapeutic apheresis and transfusion medicine consultation for transfusion service is preferred. Michigan Blood provides blood products and services for more than 70 hospitals throughout Michigan, and is an established leader in quality and service. In addition, Michigan Blood provides therapeutic apheresis, cellular therapies for the treatment of cancer and transfusion medicine consultations. We offer a competitive salary and benefit plan. If you like to work with people, have good communication and customer service skills, and the desire to make a lifesaving difference, please upload your resume and cover letter at: www.miblood.org.