Office of Blood Research and Review (OBRR) Overview

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Site Visit (LEP, LMV and LBTSEA) Report Review

Blood Products Advisory Committee
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OFFICE OF BLOOD RESEARCH AND REVIEW

Immediate Office of the Director

Acting Director
Nicole Verdun, M.D.
Acting Deputy Director
Hira Nakhasi, PhD.
Associate Director for Policy
Jennifer Scharpf, M.P.H.
Associate Director for Research
C.D. Atreya, Ph.D.

Division of Emerging and Transfusion Transmitted Diseases

Acting Director
John (Peyton) Hobson, Ph.D

Acting Deputy Director
Anne Eder, M.D.
Associate Director for Managed Review
Sayah Nedjar, Ph.D.

Product Review Branch (PRB)
Laboratory of Molecular Virology
Chief: Indira Hewlett
Laboratory of Emerging Pathogens
Chief: Sanjai Kumar
Laboratory of Bacterial and TSE Agents, Chief: David Asher

Division of Blood Components and Devices

Director
Orieji Illoh, M.D.
Deputy Director
Wendy Paul. M.D.

Devices Review Branch (DRB)
Chief: Teresita Mercado
Blood and Plasma Branch (BPB)
Chief: : COL Richard McBride

Laboratory of Cellular Hematology
Chief: Jaro Vostal
Laboratory of Biochemistry and Vascular Biology
Chief: Abdullah Alayash

OBRR MISSION

The mission of the Office is to ensure the safety, efficacy, and availability of blood and blood products

This is achieved **through regulation** of:

- Blood and blood components for transfusion, and plasma for fractionation
- Devices used in manufacture of blood and blood components (e.g., BECS*, automated cell separators, blood grouping and cross-matching reagents and devices, HLA tests)
- Blood collection containers and additive solutions (e.g., anticoagulants)
- Plasma volume expanders (albumin, dextrans, hetastarches)
- Oxygen carrying solutions (HBOCs, perfluorocarbons)
- Donor screening tests and confirmatory tests for transfusion-transmissible infections; pathogen reduction devices
- Diagnostic tests for human retroviruses

**Blood Establishment Computer System*

OBRR Functions

To fulfill our mission, we

- Establish policies and standards to assure donor safety and the safety of blood and blood products
- Review of applications for investigational and commercial use of blood products, -related devices and retroviral diagnostics
- Perform establishment inspections and assist the Agency in regulatory compliance actions
- Perform health hazard evaluations and risk assessments of blood and blood products
- Engage in emergency preparedness (e.g. Ebola and ZikaV outbreaks)
- Global outreach and cooperation
- Organize scientific workshops on timely topics important to OBRR
- **Conduct research to facilitate the development, manufacture, and evaluation of blood products and retroviral diagnostics**

OBRR Vision for Research

Supports the FDA's initiatives in regulatory science including medical countermeasures to facilitate product development through:

- Focus on scientific questions critical to effective regulation
- Concentration in areas where our unique role as regulators is most contributory
- Provision of an infrastructure for investigation of product limitations and failures
- Advancing innovation in research areas that enrich FDA's regulatory science base

OBRR Research Resources

- Subject expertise -virology, retrovirology, bacteriology, parasitology, prions, cell biology, immunology, biochemistry, and physiology
- 16 Investigator (Research-Reviewer) initiated programs located in two Divisions under five Laboratories
- Programs are mostly funded by both internal (CBER/FDA intramural) and external sources such as NIH -NIAID, NHLBI, NCI, DoD, and CRADAs

OBRR Research Goal 1

Assess and promote safety and effectiveness of transfusion products and related devices and technologies.

Objectives:

- Evaluation of ex vivo stored platelets and/ or red cells for a) safety and efficacy, b) toxicokinetics and development of biomarkers of product quality including Omics-based approaches and, c) microparticles-associated toxicities.

- Evaluation of the safety and effectiveness of oxygen carrying solutions, platelet-like products and related biologics.

- Development and evaluation of reference panels for molecular typing methods for blood groups and HLA antigens.

- Facilitate development of pathogen reduction technologies applicable to whole blood and blood components.

OBRR Research Goal 2

Assess and promote safety and effectiveness of Transfusion-Transmitted Infectious Disease (TTID) agent donor screening and supplemental tests, and retroviral diagnostics.

Objectives:

- Evaluation of screening and confirmatory technologies for detection of TTID agents for assurance and enhancement of blood safety.
- Development and evaluation of reference panels for screening and confirmatory tests for TTID agents and retroviral diagnostics.
- Facilitate preparedness for blood safety from emerging infectious agents and other pathogens of global significance through investigations of mechanisms of transmission and pathogenesis.

OBRR Global Outreach

OBRR Staff participates either as a Member or Observer in

- WHO initiatives
  - Collaborating Center for Biological Standardization
  - Expert Committee on Biological Standardization
  - Blood Regulators Network
  - Prequalification Program for diagnostics
- European Directorate for the Quality of Medicines & HealthCare, Blood Transfusion Sector
- International Society of Blood Transfusion Working Groups on Transfusion Transmitted Diseases, Hemovigilance, and Global Blood Safety
- FDA/EMA/Health Canada Blood Cluster

Concluding Remarks

- Research is integral to the mission of OBRR, CBER, and FDA

- OBRR research facilitates product evaluation and development, and is aligned with, and fulfills the regulatory science mission of CBER and FDA