

Overview of OBRR and DBCD Research Programs

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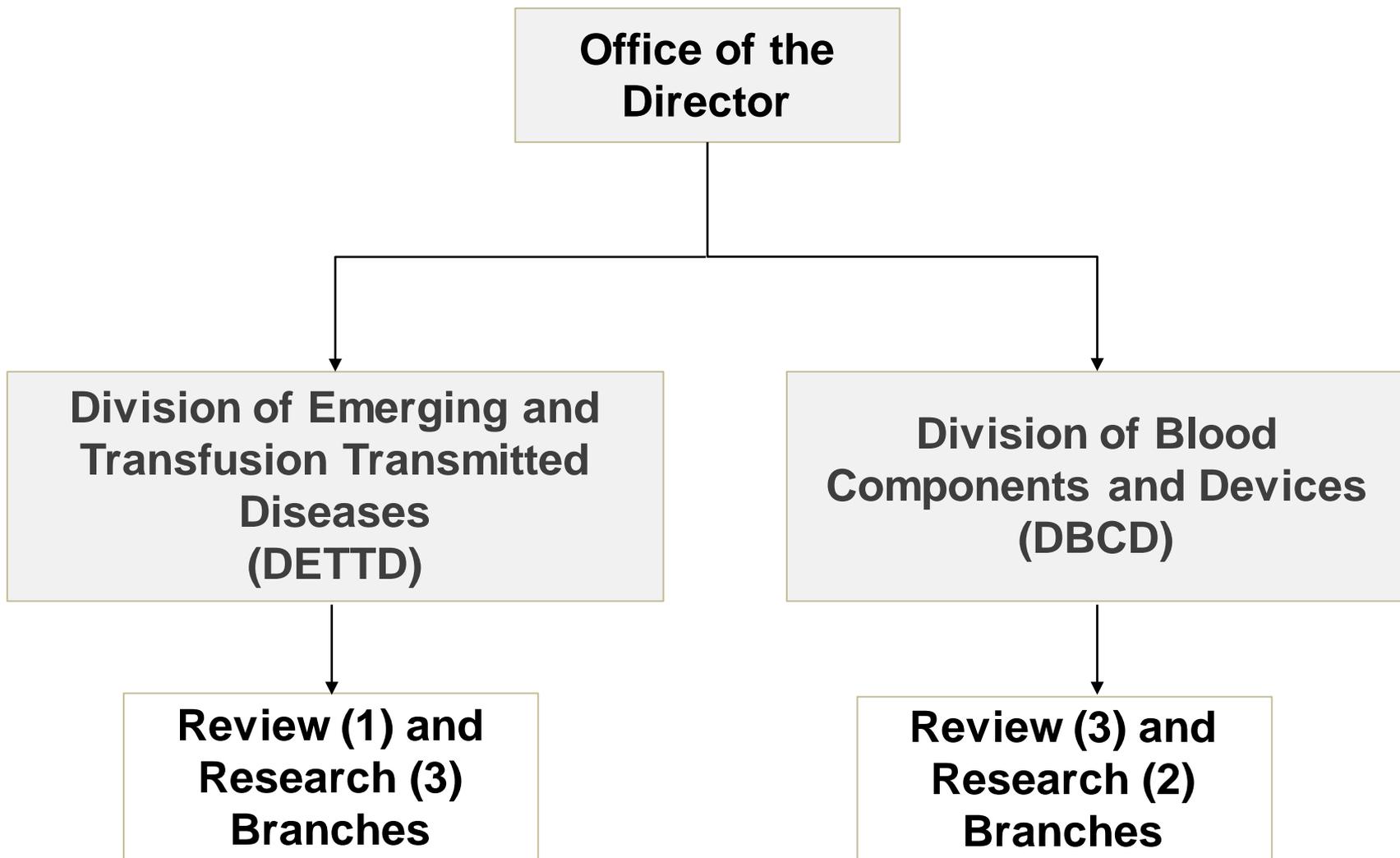
Director, Division of Blood Components and Devices

OBRR, CBER

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Office of Blood Research and Review (OBRR)



OFFICE OF BLOOD RESEARCH AND REVIEW



Immediate Office of the Director

Director
Nicole Verdun, M.D.

Deputy Director
Anne Eder, MD, PhD

Associate Director for Research
C.D. Atreya, Ph.D.

Division of Emerging and Transfusion Transmitted Diseases

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Deputy Director
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Laboratory of Molecular Virology
Chief: Indira Hewlett, Ph.D.

Laboratory of Bacterial and TSE Agents
Chief: David Asher, M.D

Laboratory of Emerging Pathogens
Chief: Sanjai Kumar, Ph.D.

Division of Blood Components and Devices

Director
Orieji Illoh, M.D.

Deputy Director
Wendy Paul, M.D.

Laboratory of Cellular Hematology
Chief: Jaroslav Vostal, MD, Ph.D.

Lab of Biochemistry & Vascular Biology
Chief: Abdullah Alayash, Ph.D., D.Sc.



OBRR Mission

Ensure the safety, efficacy, and availability of blood and blood products through regulation of:

- Blood and blood components for transfusion, and plasma for fractionation
- Blood collection containers, storage solutions, and devices used in the manufacture of blood and blood components
- Plasma volume expanders and oxygen carrying solutions
- Assays to test for transfusion-transmissible agents
- Diagnostic tests for human retroviruses



OBRR's Vision for Research

- Conduct mission relevant research to facilitate the development, manufacture and evaluation of products
 - Address scientific questions critical to effective regulation and review
 - Advance innovation in research areas that enrich FDA's regulatory science base



OBRR's Research Resources

- 16 Investigator (Research-Reviewer) programs
 - Includes expertise in virology, retrovirology, bacteriology, parasitology, prions, cell biology, immunology, biochemistry, and physiology
- Programs are mostly funded by 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:

- Evaluate *ex vivo* stored platelets and red cells for safety and efficacy (toxicokinetics; development of biomarkers of product quality; microparticles-associated toxicities)
- Evaluate the safety and effectiveness of oxygen carrying solutions, platelet-like products and related biologics
- Develop and evaluate 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:

- Evaluate screening and confirmatory technologies for detection of TTID agents for assurance and enhancement of blood safety
- Develop and evaluate 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 participate either as a members or observers 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

Overview of the Division of Blood Components and Devices (DBCD)

Division of Blood Components and Devices (DBCD)



Director: Orijei Illoh, M.D.
Deputy: Wendy Paul, M.D.

Device Review Branch (DRB)

Chief:
Zhugong
(Jason) Liu,
M.D. Ph.D.

Clinical Review Staff CRS

Team Lead:
Salim
Haddad, M.D.

Blood and Plasma Branch (BPB)

Chief:
Richard
McBride, MS

Laboratory of Biochemistry and Vascular Biology (LBVB)

Chief: Abdu I.
Alayash, Ph.D.

PIs

Abdu I. Alayash,
Ph.D.
Felice D'Angillo,
Ph.D.

Laboratory of Cellular Hematology (LCH)

Chief: Jaroslav
Vostal, M.D. Ph.D.

PIs

Jan Simak, Ph.D.
C.D. Atreya, Ph.D.
Jaroslav Vostal,
M.D. Ph.D.

Total Principal Investigators- 5

DBCD Mission

- Assure the safety, efficacy and availability of blood and blood components and related biological products
 - Blood transfusion involves multiple processes including donor screening, testing, collection, storage and compatibility testing
 - Biological products include hemoglobin-based oxygen carriers and volume expanders



DBCD Review Activities

- Review applications and perform inspections related to:
 - Manufacture of blood and blood components for transfusion and Source Plasma for further manufacture
 - Devices used in manufacture of blood and blood components
 - Immunohematology reagents for blood compatibility testing
 - Plasma volume expanders
 - Hemoglobin-based oxygen solutions/therapeutics and Fluorocarbon-based oxygen solutions
- Investigational New Drug (IND) and Investigational Device Exemption (IDE) reviews, and other pre-marketing activities

DBCD Regulatory Review Process



- Regulatory decisions are based on scientific data showing safety, efficacy and purity
 - Internal review by reviewers/ research-review staff and supervisors
 - Facility inspections
 - Presentations to Advisory Committees e.g., novel blood product or device
 - Public workshops

Additional DBCD Activities

- Develop policies governing practices related to blood donor eligibility and product manufacturing
- Serve as liaisons with industry, government agencies (e.g., NIH, CDC), regulatory agencies of foreign governments, international bodies
- **Conduct mission relevant research to facilitate the development, manufacture and evaluation of products DBCD regulates**

DBCD Research Goals and Objectives



- Assess and promote the safety and effectiveness of transfusion products
- Explore novel methods for blood product processing and evaluation

Examples include:

- Evaluate pathogen reduction technologies
- Develop animal models to evaluate cellular blood product quality
- Assess the role different biomarkers play in blood product storage and quality
- Develop novel methods to evaluate microparticles in blood products
- Evaluate the safety and effectiveness of oxygen carrying solutions

Summary



- DBCD research complements the regulatory mission
 - Enhances DBCD's ability to advance the review and development of safe blood products and related devices
 - Contributes to the development of regulatory policies for product development and review
- DBCD research staff have made significant contributions to the field and are recognized internationally for their work