

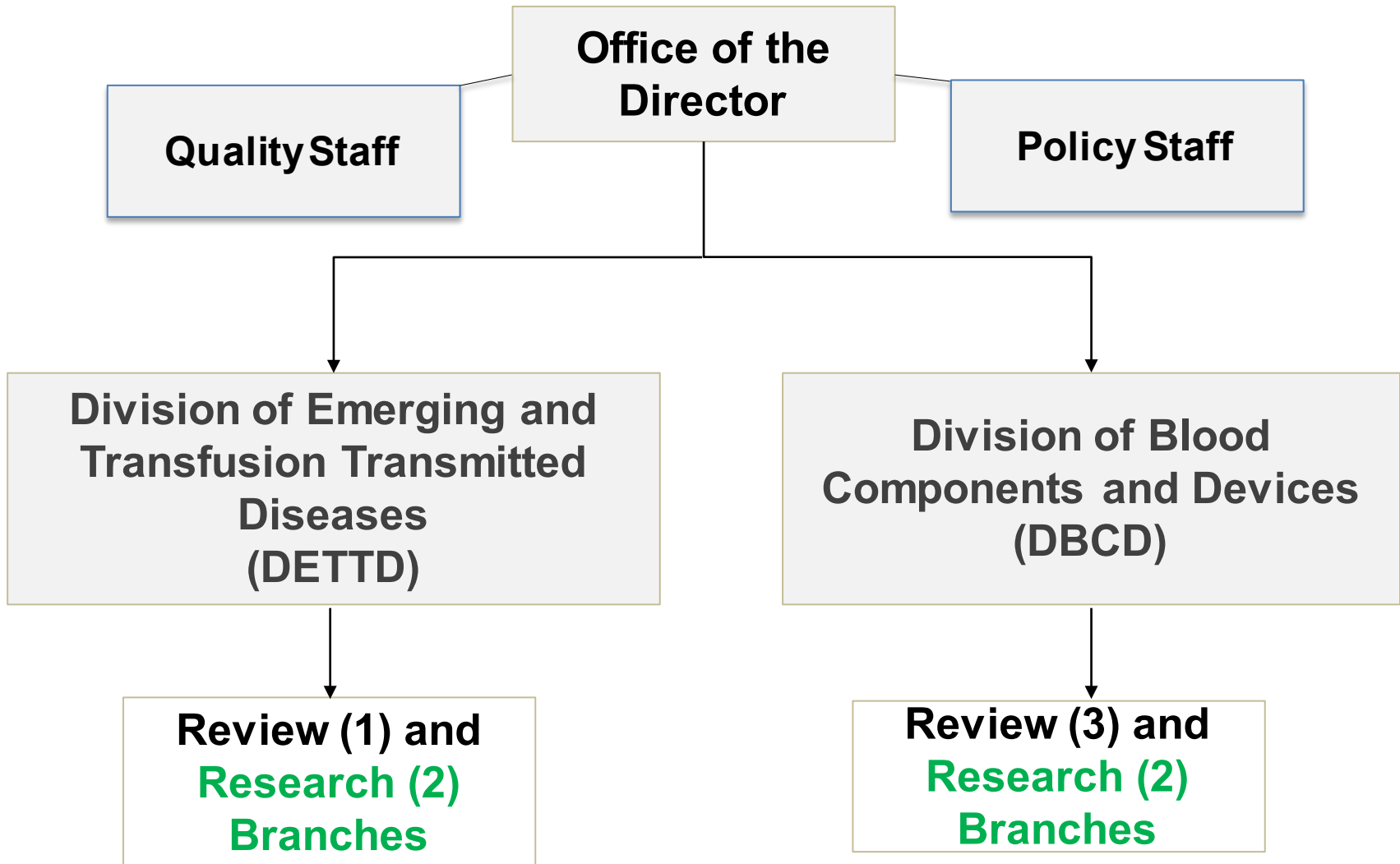
Overview of OBRR and Research Programs

C.D. Atreya, Ph.D.
Associate Director for Research
OBRR, CBER, FDA

Laboratory of Molecular Virology
Laboratory of Emerging Pathogens
Research Program Site Visit Reports review

123rd Blood Products Advisory Committee
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Office of Blood Research and Review



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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
- Devices used in manufacture of blood and blood components (e.g., blood establishment computer systems, 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)
- Serological and nucleic acid assays for blood donor screening and confirmation for transfusion-transmissible agents
- Diagnostic tests for human retroviruses
- Pathogen reduction devices for blood components



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., COVID-19 public health emergency)
- Engage in 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 Goal 1

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

Objectives:

- Evaluation of *ex vivo* stored platelets and red cells for safety and efficacy (toxicokinetics; development of biomarkers of product quality; 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 Research Resources

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



OBRR Global Outreach

OBRR Staff (review and research) 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 fulfils the regulatory science mission of CBER and FDA