Office of Blood Research and Review (OBRR)
CBER

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OBRR Mission

The mission of the Office of Blood Research and Review is to ensure the safety, efficacy, and availability of blood products.

This is achieved through regulation of:

- Blood and blood components, plasma derivatives and analogous products
- Blood donor screening tests, and other medical devices, including software used to test, collect, process, or store donated blood
- Retroviral diagnostic tests

Functions

To fulfill our mission, we

- Establish policies and standards to assure donor safety and the safety, purity and potency of blood and blood products
- Review of applications for investigational and commercial use of blood products, blood-related drugs and devices and retroviral diagnostics
- Perform establishment inspections and product investigations with OCBQ and ORA, and assist 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 outbreak)
- 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

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, toxicology, immunology, biochemistry, physiology, hematology and pharmacogenetics
- 26 Investigator (Research-Reviewer) initiated programs located in two Divisions under seven laboratories
- Programs are mostly funded by both internal (FDA Mod Sci, MCMi, CP, Panflu, FDA-Nano, OWH, OMH) and external sources (NIH -NIAID, NHLBI, NCI, CC; CRADAs; BARDA)

OBRR Research Goals (3) and Objectives (13) (2016-2020)

Goal 1 (3 Objectives)

Assess and promote safety and effectiveness of approved and in-development transfusion products

- 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 impact of different manufacturing processes on the quality of plasma proteins

- Evaluation of the safety and effectiveness of “blood substitutes” including hemoglobin-based oxygen carrying solutions, platelet-like products and related biologics

OBRR Research Goals (3) and Objectives (13) (2016-2020)

Goal 2 (4 Objectives)

Assess and promote safety and effectiveness of approved and in-development injectable products

- Development of approaches for predicting immunogenicity of protein based therapeutics based on MHC and mutations in deficient patients; and study of immunogenicity of replacement coagulation factor therapies
- Studies of codon optimized recombinant coagulation proteins to assure that increased yield does not affect safety or efficacy
- Evaluation of the safety and efficacy of plasma-derived products and their recombinant analogs including measures of potency and risk factors for adverse reactions
- Characterization of virus neutralizing antibodies in immune globulin products

OBRR Research Goals (3) and Objectives (13) (2016-2020)

Goal 3 (6 Objectives)

Assure and promote safety and effectiveness of retroviral and other infectious agent diagnostics, donor screening tests including development of standards, and other devices and technologies used to in manufacture and quality control of blood products

- Understanding the mechanism of transmission and pathogenesis of retroviruses, hepatitis viruses, newly emerging and re-emerging blood-borne arboviruses and selected neglected and tropical disease agents to develop effective strategies to combat these pathogens

- Maintaining biologics and other FDA-regulated Products free of the infectious agents of transmissible spongiform encephalopathies (TSE Agents or Prions) and development of strategies for detection and removal of these agents from blood

OBRR Research Goals (3) and Objectives (13) (2016-2020)

Goal 3 (6 Objectives)

Assure and promote safety and effectiveness of retroviral and other infectious agent diagnostics, donor screening tests including development of standards, and other devices and technologies used to in manufacture and quality control of blood products

- Development and evaluation of reference panels for blood group molecular typing methods
- Advancing the development of diagnostic technologies for detection of transfusion-transmitted EID agents for enhancement of blood safety
- Development and evaluation of reference panels for emerging viral agents diagnostic/screening tests
- Facilitate development of pathogen reduction technologies applicable to Whole Blood and Red Blood Cells

OBRR Research Accomplishments FY15

- 87 Publications in peer-reviewed journals
- $2.5 Million intramural funding
- $1.8 Million funding from NIAID, NHLBI, DoD/DTRA
- $1.0 Million funding through CRADAs
- 3 Cooperative Research and Development Agreements (CRADAs) were established
- Supported 63 contract research staff through this funding (ORISE fellows)

OBRR Accomplishments -Global Outreach

- Participant/Member/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 and CBER

OBRR research facilitates product evaluation and development (where feasible), and is aligned with the regulatory science mission of CBER and FDA

Thank You!