



## PACT Application: Scope Criteria

The National Heart Lung and Blood Institute (NHLBI) has a longstanding commitment to moving cell therapies forward in the treatment of diseases of the heart, lung, blood, blood vessels and blood resources. The NHLBI-funded program, Production Assistance for Cellular Therapies (PACT), was formed to advance cellular therapy research in the areas of heart, lung and blood cellular therapy research. PACT is charged with providing assistance for cellular therapy translational research and the manufacture of cellular therapy products that aid in the repair and regeneration of damaged/diseased tissues, organs, and biologic systems. NHLBI welcomes applications involving cardiovascular repair and disease, lung repair and disease, hematologic disease and hematopoietic cell transplantation, **outside** of primary treatment for malignancy. PACT will consider applications requesting services for cGMP manufactured cellular products involving proof-of-principle, but IND-enabling translational research in heart, lung, blood and sleep indications. The following table lists some broad areas of programmatic interest for PACT.

NHLBI Program Areas of Interest		
Heart Development, Function and Disease	Sleep Disorders	Sickle Cell Disease
Vascular and Lymphatic Biology	Cystic Fibrosis	Developmental Biology and Pediatric Lung Disease
Rare and Pediatric Cardiovascular Disease	Red Blood Cell Disorders	Hematopoiesis and Stem Cell Biology
Peripheral Arterial Disease, Critical Limb Ischemia and Therapeutic Angiogenesis	Lung Cell and Vascular Biology	Innate and Adaptive Immunology related to Heart, Lung, Blood, Sleep Diseases and Disorders
Acquired Immunodeficiency Syndrome and Tuberculosis	Pulmonary Immunology and Fibrosis	Molecular Genetics related to Heart, Lung, Blood, Sleep Diseases and Disorders
Congenital Heart Defects	Thrombotic Disorders	Heart, Lung and Hematopoietic Transplantation
Critical Care, Trauma and Acute Lung Injury	Hemorrhagic Disorders	Asthma, and Chronic Obstructive Pulmonary Disease

### Areas of Shared Interest

NHLBI shares many areas of interests with other NIH Institutes. NHLBI's interests lie with the development, structure and function of heart, lung and blood organ systems in normal and diseased states, as well as any disease or dysfunction of other closely related organs and systems where the problem is primarily cardiac, vascular, pulmonary or blood related.

The following information identifies certain aspects of shared research interest that NHLBI will consider supporting through the PACT program. Please note that the information below is not inclusive and not all NIH Institutes and shared interests are represented. **Each application to PACT will be considered on an individual basis.**

#### *NIH Regenerative Medicine Innovation Projects (RMIP)*

The PACT program has a shared mission with the **NIH Regenerative Medicine Innovation Projects (RMIP)** program to support clinical research studies aimed at furthering the field of regenerative medicine using adult stem cells. NIH Institutes and Centers participating in the RMIP Funding Opportunity Announcements (FOA) (<https://www.nih.gov/rmi/funding-opportunities>) will determine the mechanism for support of assistance services in the development of clinical-grade cell product including use of PACT services. RMIP applicants are encouraged to consult early in the application process with the relevant Scientific/Research contact listed in the FOA for further information about using PACT.

#### *National Cancer Institute (NCI)*

- Studies of effects of primary tumors of the heart on cardiac function and in non-tumor dependent angiogenesis.
- Studies of the circulatory system and lungs, tumors affecting cardiovascular or pulmonary regulation.
- Studies on hematopoietic transplant or novel cellular therapies for repair and regeneration of heart, lung, and blood diseases.
- Autologous and allogeneic transplant or cellular therapies for hematologic disorders.



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### *National Institute of Allergy and Infectious Diseases (NIAID)*

- Studies involving infectious agents including HIV, or immunologic responses where the cardiovascular, pulmonary or hematologic systems are the major targets of investigation.
- Studies of the immunology of transplantation of the heart or lung, including but not limited to studies of acute or chronic rejection, immune tolerance in the setting of heart or lung transplantation and transplantation of genetically engineered hearts or lungs.
- Studies of hematopoietic cell or progenitor cell transplantation and its complications.

### *National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)*

- Studies dealing with the etiology and pathogenesis of hypertension, diabetic vascular or kidney disease and their effects of hypertension; endocrine regulation of the cardiovascular system; diabetes-related cardiovascular complications; treatment and prevention of cardiovascular disease; target organ damage (e.g., kidney, heart, generalized vascular abnormalities, and cerebrovascular disease) as a function of chronic high blood pressure.
- Research that pertains to growth factors important in megakaryocytopoiesis and platelet production.
- Research focused on the genetics, etiology, pathogenesis, treatment, and psychosocial needs of the pulmonary manifestations of cystic fibrosis.

### *National Institute of Neurological Disorders and Stroke (NINDS)*

- Applications dealing with cerebrovascular biology and its diseases or blood disorders involving the cardiovascular system.
- Applications that involve cerebrovascular disease, abnormal blood flow, and disturbances in vascular biology.