

PACT Program Overview and Highlights

Laarni Ibenana

Project Manager

Production Assistance for Cellular Therapies

After 18 years of support from the National Heart, Lung, and Blood Institute (NHLBI), the Production Assistance for Cellular Therapies (PACT) program is coming to a close with Coordinating Center operations ending on June 30, 2021 and remaining open Task Order Award projects at the 5 PACT Cell Processing Facilities wrapping up by March 2022. The website and all its resources will be brought down by no later than June 30, 2021.

The objective of the NHLBI PACT program is to promote the advancement of clinical research using cellular therapies for replacement or regeneration of damaged/diseased cells, tissues, and organs. We have endeavored to promote interest in cellular therapy/engineering among physicians and scientists-in-training and to prepare interested individuals for academic careers in cellular therapy/engineering.

PACT Services

PACT, in its final iteration, supported cell therapy product development in three broad areas of translational services, clinical manufacturing services, and regulatory services (Fig. 1) within the NHLBI program purview of diseases and indications.

Cell Manufacturing for IND-enabling and Early Phase Clinical Studies

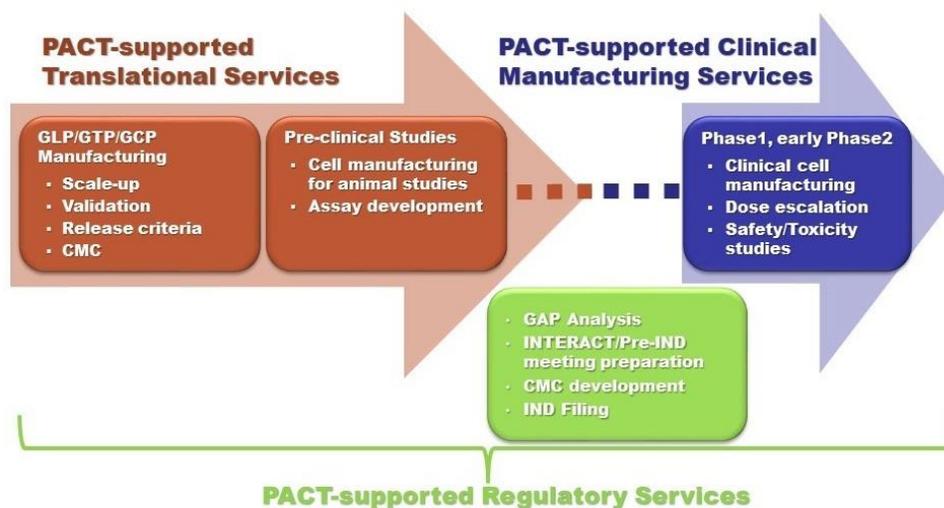


Figure 1. PACT Cell Therapy Product Development Support

PACT Organization

The Emmes Company, LLC, has served as the Coordinating Center throughout, and over the years several centers have been awarded as PACT Cell Processing Facilities; currently the 5 CPFs and program organization is as follows (Fig. 2)

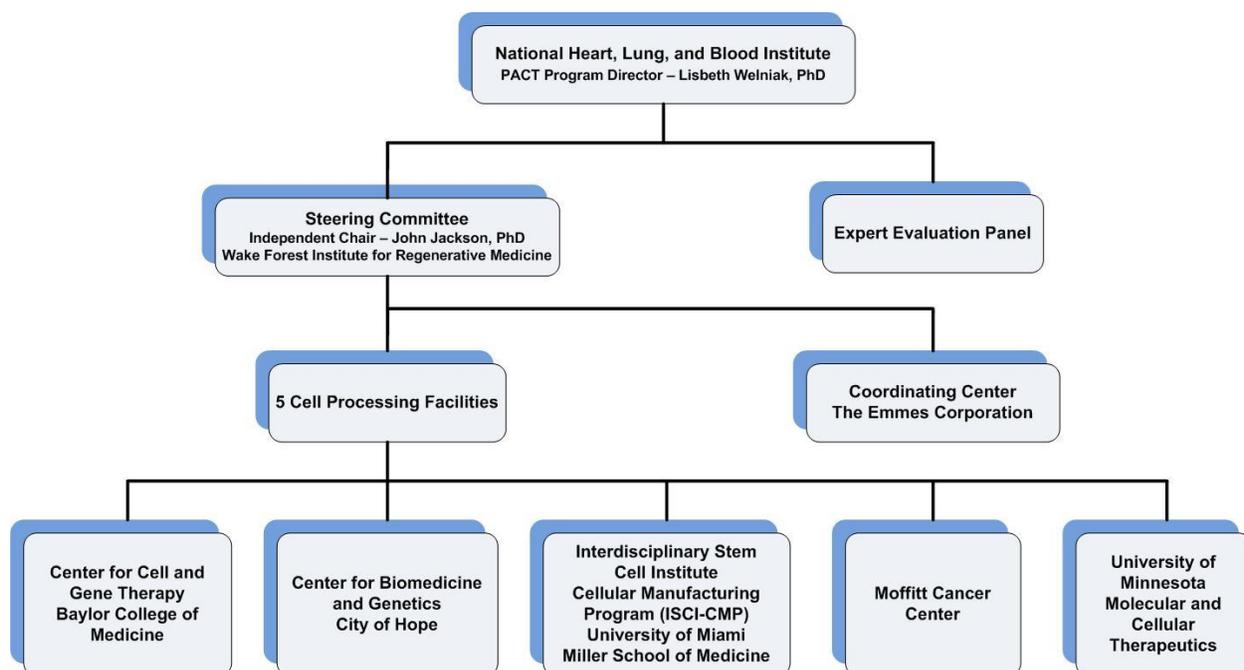


Figure 2. PACT Organization Chart

PACT by the Numbers

We are gladly sharing some highlights of the program as well as recent accomplishments and contributions to the field of cell therapy. Over the past 18 years, we have provided support for:

PACT Request for Service Applications

- 133 full (clinical or translational) applications supported/awarded to PACT CPFs
- 27 regulatory projects with the following types of support:
 - 27 Gap analysis, support for 4 INTERACT meetings, 5 pre-IND meetings, an initial IND submission and 2 subsequent IND amendments, and numerous calls and correspondence to provide follow-up regulatory support for investigators
- Eight technical projects – multi-site projects to identify and evaluate important new technologies and/or assess current methods to advance the field.

- Over 80 publications related directly to PACT-awarded projects, using PACT-manufactured products, or related to the PACT program

PACT Education and Outreach

- 35 PACT-hosted web seminars; many with free Continuing Education credits offered; including topics on Regulatory- IND Submissions/CMC/Inspections, Validation/Equipment/Facility Operations, Contract Management, Technical- Cryopreservation/Release Testing/Cell Culture and Product Development
- 9 PACT Workshops (1- or 2-day events)
- Support and contributions for chapters/books
 - Cell Therapy: cGMP Facilities and Manufacturing 1st edition (2009) and revised edition coming soon in Summer 2021
 - Hematology: Basic Principles and Practice, 7th Edition
 - Cellular Therapy: Principles, Methods, and Regulations, 2nd Edition (AABB)
- PACT Quarterly Newsletters
- Numerous PACT-sponsored presentations at relevant scientific meetings and conferences such as at AABB, ISCT and others.
- Website which served as a resource center with useful links and information for cell therapy researchers
- Received and provided over 485 SOP requests from interested researchers internationally. SOP categories:
 - Cleaning Procedures
 - Deviation Management
 - Environmental Monitoring
 - Personnel Training
 - QA/QC
 - Quality Management
 - SOP: Development and Management
 - Validation Process

Lessons Learned and Future of Cell Therapy

We have learned so much interacting with researchers at scientific meetings, working with the various CPFs, and of course collaborating with the researchers and investigators that we have sought to provide support for their cell therapy product development over the years. The PACT program submitted a paper recently accepted for publication in *Clinical and Translational Science* which discusses some of these lessons learned. We hope that even though the PACT program is ending, there will be many more great accomplishments from others in this field and that we can serve as a springboard for potential program in the future to even more so bring advances to the science. We also recently supported Dr.

Adrian Gee with the submission of the final manuscript for the 2nd Edition of the Cell Therapy: cGMP Facilities and Manufacturing book, set to release in Summer 2021, which we wanted to make you aware of and which we also hope will be a valuable resource in the hands of new and experienced researchers (you!). We are confident that the future of cell therapy is promising, with recent advancements and milestone approvals, the good foundations that have already been laid down, and increasing interest in this field. There is more work to be done!

Finally, we would like to thank Dr. John Jackson from the Wake Forest Institute for Regenerative Medicine who has presided over us in our last contract iteration as the Steering Committee Chairperson. He along with Dr. Lis Welniak, Dr. Traci Heath-Mondoro, Dr. Robert Lindblad, and Dr. Robert Anderson have provided leadership to the program that has led to its success.