

APPLICATION PROCESS



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Production Assistance for Cellular Therapies
National Heart Lung and Blood Program


PACT Application Process

- Web-based Application
 - Scope Review by NHLBI
 - Full Application invited if scope is approved
- Scientific Review Board Review & NHLBI Vote
- TO-RFP issued; competitive bids
- TO awarded (1 CPF)
- Contract, Timeline & Budget

Scope Review Application Content

- Investigator information (Biosketch, CV, etc.)
- Scope
 - Relevance to NHLBI scientific interests and PACT Scope
- Proposal Overview
 - Synopsis of proposed study

Full Application Content

- Investigator information (Biosketch, CV, etc.)
 - Scope - Scientific interest and programmatic scope
 - Proposal Overview
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- Scope Review
- Product information
 - Current funding - *product manufacturing and other activities/tasks not covered by PACT.*
 - Manufacturing information
 - Production methodology
 - Product development
 - Regulatory information
 - Timeline
 - Estimated budget
 - Institutional/Organizational business office information

Application Review/Criteria

- NHLBI and an external, independent Scientific Review Board (SRB) comprised of cell therapy experts review:
 - Relevance to the scientific mission and programmatic scope
 - Applicant and the collaborative team qualifications
 - Evaluation of the strengths and weaknesses of preliminary data, manufacturing feasibility, significance to the field, degree of innovation, and overall scientific merit of the application
 - Detailed translational development plan summary
 - Product specifications (proposed release criteria and potency assay)
 - Supplemental manufacturing funding
 - Demonstration of an adequate plan for eventual use of the cell therapy product in a clinical trial
 - Proposed work supports regulatory pathway for this product

Next Steps

➤ Contract

- Contract negotiations with designated facility
 - Intellectual property and/or indemnification

➤ Timeline

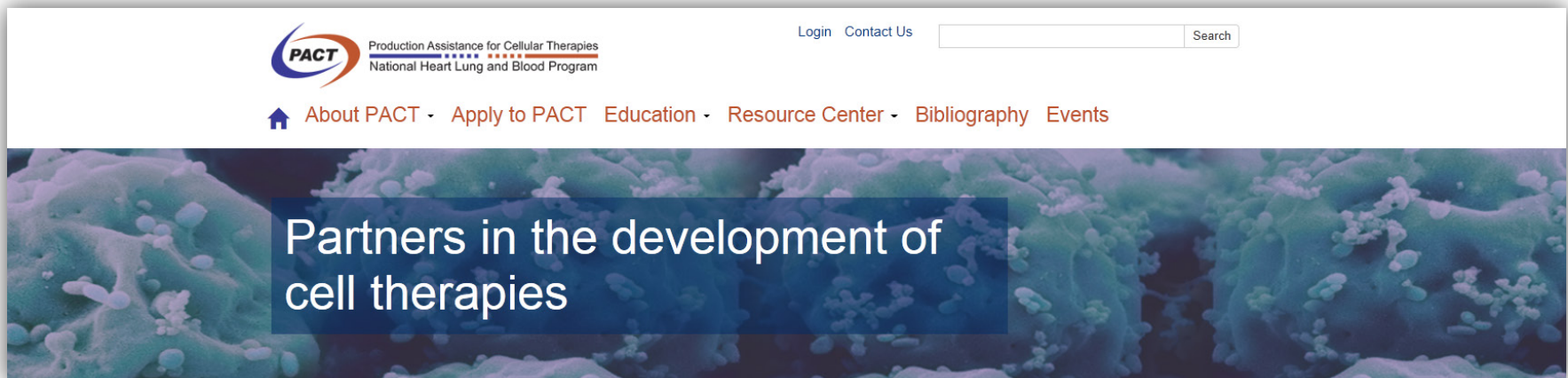
- Development of production task order
- Scheduling of manufacturing tasks
- Scheduling of production

➤ Budget

- CPF assistance

Website

- www.pactgroup.net
 - Online application process and information
 - Education Initiatives
 - Events/Updates
 - Links to PACT facilities, regulatory references & other resources



Contact Information

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Q & A