



## Call for Investigator-Initiated Collaborative Grants in Cell Manufacturing

**Submission Deadline: December 12, 2016**

The Marcus Center for Therapeutic Cell Characterization and Manufacturing announces the 2016-2017 research grant program. This funding mechanism is intended to stimulate new, collaborative research in cell manufacturing and to encourage scientists and engineers from diverse fields to come together, ask important questions, and solve important and transformative problems related to the challenge of cell manufacturing. Please refer to the MC3M website at <http://www.cellmanufacturing.gatech.edu/> for information about the Marcus Center and its mission and vision. Please also review the Cell Manufacturing roadmap that Georgia Tech led and helped put together, at the National Cell Manufacturing Consortium's Website [www.cellmanufacturingusa.org](http://www.cellmanufacturingusa.org).

Each proposal must have a minimum of one investigator from Georgia Tech. Additional co-investigators from either Georgia Tech or other institutes are welcome. Multi-investigator proposals demonstrating convergence of multiple expertise will be favored. Please note that in case of investigators outside of Georgia Tech, a sub-contract can be issued or usage/service fee based model can be used. All funds originate at Georgia Tech and as such the PI must be associated with Georgia Tech.

This funding mechanism is intended to fund projects at earlier stages of development, however projects that already have a proof of concept system and wants to scale-up or develop further for translation, will also be considered.

Budgets for these proposals should not exceed \$100,000 per year (for up to two years) including personnel cost and material/supplies. Equipment cost will be considered on a case by case basis, but are generally discouraged. There is no indirect cost associated with this at GT, except for overhead on sub-contracted amounts charged by other institutions. A total of 5 grants are expected to be awarded.

Proposals can be for one year or two years with appropriate justification for the proposed project duration. All projects must provide a detailed milestone and an aggressive but realistic timeline to achieve those milestones. All projects will be reviewed every 6 months by the Marcus Center executive committee to ensure adherence to timeline and performance. Non-performing projects could be terminated after providing feedback and time to correct deficiencies.

### Topics

Proposals responsive to the following research topics will be given funding priority, however other areas especially those related to topics discussed in the cell manufacturing roadmap will be considered.

1. Development of sensors or other cell-analysis tools for longitudinal, real-time monitoring of cell function or properties.
2. Development of sampling probes for cells and cell-media to interface with analytical devices.
3. Development of microfluidic organ-on-a-chip or device-on-a-chip to test potency (safety and efficacy) of cell therapies.
4. Development of algorithms and data analytic methods or predictive modeling tools for identification of critical quality attributes (CQAs) or biomarkers for cell therapeutics.

5. Development of new imaging and image-analytic tools for continuous monitoring of cell sensors or cell properties during manufacturing; especially under 3D or bioreactor culture conditions.
6. Development of novel supply chain and process modeling algorithms and methods for cell therapy manufacturing and distribution.

## Deadline

The deadline for submission of proposals is **Monday, December 12, 2016, 9:00 AM Eastern Time**. Awards will be announced by January 13, 2017 with a funding start date of January 15, 2017

## Submission & Questions

Technical questions regarding the proposal may be addressed to **Andrea Soyland** at [andrea.soyland@ibb.gatech.edu](mailto:andrea.soyland@ibb.gatech.edu). Technical questions regarding the appropriateness of a proposal topic or its direction may be addressed to Krish Roy, at [krish.roy@gatech.edu](mailto:krish.roy@gatech.edu)

Proposals should be emailed **as a single PDF document as per instructions below, to the following email: [andrea.soyland@ibb.gatech.edu](mailto:andrea.soyland@ibb.gatech.edu)** . Please also cc [krish.roy@gatech.edu](mailto:krish.roy@gatech.edu)

## General Guidelines

### ELIGIBILITY

- All faculty members with primary appointments at Georgia Tech are eligible to apply as PI. As mentioned above, Co-PIs can be from any other institution(s) in Georgia or outside. Please keep in mind that sub-contracts may be subjected to F&A charges by the partner institutions.
- Proposals from investigators who are new to the cell manufacturing field and/or those addressing new questions or taking new approaches are encouraged.

### ADDITIONAL DETAILS

- Applications are for up to a maximum of two years of funding subject to six month reviews as stated above.
- Funds may be used for Ph.D. student/postdoc support, animal studies, supplies, and limited travel as related to the conduct of the research. Tuition can be charged if needed. Faculty salary is also appropriate when justified. Funds may not be used to pay any costs associated with institutional overhead at GT.
- **Applicants are reminded that these are NOT seed grants** intended to promote the acquisition of extramural funding, but as milestone-driven R&D projects intended to build new tools and methods to enable better cell manufacturing. Of course subsequent extramural funding can be pursued at the discretion of the investigators when appropriate.
- Application does not have to be hypotheses driven; design driven applications are encouraged as well.
- Projects may be renewed for a 3<sup>rd</sup> year of funding under limited circumstances based on results and progress.
- The success of this research grant program will be measured by achieving milestones and

products, generation of intellectual property, and/or progress towards clinical or industrial translation. Publications arising from a grant funded by this program are required to acknowledge the source of funding by including the following statement: "This work was funded through the Marcus Center for Therapeutic Cell Characterization and Manufacturing, The Georgia Tech Foundation, and the Georgia Research Alliance."

- All proposals are limited to a maximum of 5 pages of research description (excluding bibliography). The description must say what critical unmet need in cell manufacturing is being addressed and what cells are being used/investigated. **Please note:** The Marcus Center has access to clinically relevant cells obtained through clinical partners which can be made available to investigators at no cost. Please contact Krish Roy ([krish.roy@gatech.edu](mailto:krish.roy@gatech.edu)) to discuss. Any adult-derived therapeutic cells are appropriate to use but preference will be given to Mesenchymal progenitor cells from bone marrow, cord tissue, perinatal tissues or adipose tissues; immune cells e.g. therapeutic T cells or B cells, hematopoietic stem cells, iPS cells. Preference will be given to using human cells although proof of concept using animal cells and models are welcome.
- In addition to these 5 pages, a one page milestone and deliverable chart with six-monthly timeline is required. Please use Arial 11 point font, 1 inch margins.
- Applications should also include a 2 year budget (divided into Year 1 and Year 2 and with clearly separated categories for personnel and M&S) with justification. Budgets are in addition to the 5 page research section.
- An NIH format biosketch or a short CV (not to exceed 4 pages) for all investigators (see specific instructions section below) must be included.

#### DETAILED FORMATTING INSTRUCTION

All Applications must include (as a single PDF document):

1. Cover page with the following information:
  - i. Title of Project
  - ii. Applicant Name(s), Titles, Email Addresses
  - iii. Department, Institution
  - iv. Requested Award Amount (Direct Costs)
2. An abstract (no more than 250 words)
3. 5 page Research section as described above
4. 1 page Milestone/Deliverables chart as described above
5. Biosketches of all key personnel as detailed above
6. Budget with justification. (Funds may be used for data collection and analysis, research lab supplies, and faculty/student/postdoc/technical support that are directly related to the conduct of the research. Salary support for hospital medical/nursing staff, or administrative support is not appropriate.)
7. A statement on Human Subjects Protection, as outlined in the PHS 398 instructions (if applicable).
8. The following items (provided within 60 days from notice of award (if relevant): IRB approval letter, Approved IBC protocol, IACUC approval. Any additional relevant certifications (CITI, etc.)