

Waisman Biomanufacturing Reduced Pricing Program for UW Investigators

Waisman Biomanufacturing is launching a new program that will provide reduced pricing for UW investigators involved in the development of biotherapeutics including: cell therapeutics, gene therapeutics (plasmid DNA, viral vectors), vaccines, and recombinant proteins. The goal of this program is to facilitate the ability of UW investigators to advance promising biotherapeutics into human clinical trials. In addition, we anticipate that advances in biotherapy development that are achieved through this program will aid UW investigators in securing future funding from NIH and other granting agencies to support continued development.

ELIGIBILITY

UW-Madison investigators that obtain funding through peer-reviewed programs including UW pilot programs (e.g., Fall Competition, UW2020, ICTR Pilot Awards, Comprehensive Cancer Center or school/college-based competitions), NIH (or the equivalent), or foundation grants are eligible for this program. Funding sources not mentioned here will be considered on a case-by-case basis. Funding cannot be through non-peer reviewed programs, nor can it be via a contract. Applicants must outline the pathway to human clinical trials with a reasonable estimate of project scope and financial requirements to address pre-clinical animal studies, filing of an Investigational New Drug (IND) or Investigational Device Exemption (IDE), human clinical trials, and a plan for securing the required future funding.

Determination about eligibility for reduced pricing will be made by a group consisting of Waisman Biomanufacturing's director and manager of business development, along with the Waisman Center's director and associate director for administration and finance, in consultation with others as needed.

REDUCED PRICING

UW investigators with projects deemed eligible according to the above criteria will be offered a budget that contains a waiver of fees other than salary/fringe benefits and the cost of materials. Per diem fees on use of clean rooms as well as the "other direct cost" category will not be charged.

PROGRAM SERVICES

Waisman Biomanufacturing provides comprehensive services for translational researchers that are focused on moving their biotherapeutic into human clinical trials. Investigators should engage WB early in their translational research programs to discuss their project and help insure a smooth transition into clinical trials. WB offers the following services to support projects from the early research stages through to clinical trials:

- Consultation on product development plans
- Manufacturing process development
- Quality Control method development
- Production of material for pre-clinical testing programs
- Production clinical trial material under current Good Manufacturing Practices (cGMPs)
- Support for IND/IDE filing

APPLICATION PROCESS

Investigators that are applying for funding through peer-reviewed funding programs should consult with WB prior to submitting their application. WB can provide input on the translational development plan for the biotherapeutics candidate and will provide a budgetary estimate that can be used in the application along with a Letter of Support. This budget will include pricing for services at the reduced rate (salary/fringe + materials cost, no room fee) to allow investigators to move their programs further into clinical development on a limited budget.