

cGMP/cGTP CELL PROCESSING REQUEST FOR SERVICE

Date: _____

Principal Investigator/Sponsor: _____

UM Department: _____

Telephone: _____ Mobile: _____

E-mail: _____

Address: _____

A. Request Type

- cGMP development / scale up, not for clinical use
- cGMP/cGTP development / scale up, specifically for clinical trial

B. Product Information

- Attach product description: cell type and/or active components, source of product (unrelated, related, or autologous donor; tissue type; cell line or other pertinent details), proposed use/clinical indication, and indicate the time when the product will be needed (month/year)
- Need assistance with the above
- Has this product been used in previous clinical trials? No Yes

C. Manufacturing Information

- Manufacturing Protocols
- Reagents list required to manufacture the product showing amounts and costs
- Supply list required to manufacture the product showing amounts and costs
- Equipment list required to manufacture the product
- Product specifications (potency, purity, sterility, endotoxin, function, dose, etc)

D. Regulatory and Clinical Information

- Do you have an IND for the product and/or clinical study?
 - No Yes; If Yes, IND # _____; Copy of IND package
 - If No, do you need regulatory assistance to file one? No Yes
- Do you have IRB approval?
 - No Yes; If Yes, IRB # _____; Copy of IRB approval
 - If No, do you need regulatory assistance to file one? No Yes

E. Contractual Considerations

- Disclosure of any contractual obligations (e.g., research or clinical research agreement, MTA, CDA, etc.).

F. Liability

- Any Liability Issues

TERMS AND CONDITIONS FOR THE USERS OF THE WALLACE H. COULTER CENTER cGMP/cGTP FACILITY

WHEREFORE, the Wallace H. Coulter Center (hereinafter referred to as "WHCC"), requires every user of its services and facilities to become familiar with the procedures for use of the facilities as outlined in this memorandum of understanding and hereby acknowledge the procedures by signing this memorandum of understanding..

WHEREFORE, the use of the cGMP/cGTP facilities require extensive input from the Principal Investigator ("PI") and WHCC staff members during the initial and validation phases.

NOW, THEREFORE, for good and valuable consideration, the sufficiency of which is hereby acknowledged, WHCC and PI agree as follows:

- A. For submission of requests for services for the cGMP/cGTP facilities, the following items are required:
 - 1. Description of the product's intended use
 - 2. Protocols for cell manufacturing and testing
 - 3. Approximate cost of reagents, supplies, etc
 - 4. Special Equipment or other special requirements
 - 5. Product release criteria
 - 6. Copies of the IRB and IND approvals
 - 7. Disclosure of any contractual obligations (e.g., research or clinical research agreement, MTA, CDA, etc.). Please attach a copy of the agreement to this form.
 - 8. Disclosure of liability issues. If there are any liability issues, please explain.
- B. Should failures and/or mistakes occur, discussion of fees will be handled on an individual basis in consultation with the PI. All circumstances surrounding the event will be fully examined and considered before making a decision.
- C. The WHCC reserves the right to amend this agreement, services provided, and fees charged with notice prior to the commencement of services requested.

PI/Sponsor Name: _____

Signature: _____

Date: _____

WHCC Laboratory Manager: _____

Signature: _____

Date: _____

**Please fax all pages to
Dr. Jose Da Silva at 305-243-1042.**

For questions regarding services, please call 305-243-9497.