APPLICATION FOR PROJECT IN BIOLOGICS PRODUCTION FACILITY
University of Nebraska Medical Center

PROJECT TITLE: _____

Submitted by: _____ DATE: _____

Collaborators:

Research Collaborators: _____

Clinical Collaborators: _____

Type of Relationship to UNMC/TNMC:

- UNMC investigator; Department: _____
- Eppley Institute Investigator
- Company / Contract Name of Company: _____
- Other: _____

Define relationship to UNMC/TNMC patients (Clinical sites)

- UNMC/TNMC patients will receive all products
- Some patients will be at UNMC/TNMC; other institutions are involved
- No patients at UNMC/TNMC will be involved

Name / type of product: _____

Investigational New Drug Application (IND):

- IND number and Title (include copy of approval): _____
- Under review/revision
- Under development
- Not required

Institutional Review Board (IRB) submission:

- Approved. Protocol #/Title: _____
- Submitted; under review/revision
- Under development
- Not required

Does the project involve:

Animal material in the production?
Radioactive components?
Toxic reagents or materials in manufacture?
Patent or copyright issues?

Does the project include collection of a starting product, such as marrow, apheresis-derived cells, solid organs?

Trial Phase:

Phase 1 Phase 2 Phase 3

Will the project include a product that will be administered to patients of UNMC / TNMC? YES NO

Number of patients proposed to be treated: _____

If there are clinical sites other than UNMC/TNMC, list these. _____

This is to assist with planning for logistics and liability issues.

Financial support for project from: _____

Abstract/Summary of project:

Scientific Proposal:

Include current state of product development, clinical protocol, number of products/patients.

Is scale-up required?

Have animal trials been completed if necessary?

Production SOP: include a copy that includes a description of equipment required and an estimate of the size of space needed for all phases of the manufacturing.

Resources required:

- Staff

  Will you and/or your staff be available to teach any procedures necessary for production?

  Is the process amenable to technology transfer to capable scientists?

- Equipment (list)

  The facility is equipped with general laboratory equipment. Is any particularly specialized equipment required?

  If yes, can investigator provide or fund it?

- Reagents required

- Supplies and materials required

- Apheresis collections included?

GUIDELINES FOR BIOLOGICS PRODUCTION FACILITY OPERATION:

1. This is a biologics production facility, not a research laboratory.
   - Projects must involved manufacturing steps that require the regulatory and environmental controls present in the facility.
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2. All projects will be evaluated according to the approved algorithm.

3. Investigator proposing a project is responsible to define / obtain funding.

4. Generally, priority will be given to projects that address institutional priorities and support institutional clinical programs.

5. PROJECT PRIORITY (generally)
   A. Projects that involve UNMC/TNMC patients.
   B. UNMC/Eppley research/investigator without UNMC patients.
   C. Contract manufacturing.

6. Only GMP-trained personnel will work in the facility.
   - Investigators and/or their staff may advise production staff.
   - If it is necessary for any investigator-designated staff person to participate in manufacturing processes for purposes of training and technology transfer, that staff person must first complete training in basic GMP principles and practices, follow all facility policies and SOPs, and be accountable to the Operations Manager for time and activities in the facility. Such persons will not function independently within the facility.

7. Facility personnel will report directly or indirectly to the Operations Manager.