

CT POD Clinical Trial Request Form

To be completed and submitted to the CAR-T Steering Committee

PI Name: _____ Date: _____

Trial name: _____

Sponsor: _____

Disease(s) to be treated: _____

Type of therapy:

CAR – Target: _____ Gene Therapy Target: _____

TIL Other:: _____

Patients impacted: Adults Pediatrics

Has PI run a study through CT POD before? Yes No

Competing trials or commercial products (please elaborate benefit or prioritization strategy if yes):

No Yes, _____

Yearly Accrual Goal: _____ Number of Months Projected to Stay Open: _____

Sponsor Type: LCCC IIT Cooperative group/Consortium Industry Other: _____

Collaboration (check all that apply, and feel free to elaborate below): Provides support for LCCC correlative research Inter-institutional collaboration Collaboration outside of LCCC within UNC Involves named consortia (Alliance, ACCRU, BMTCTN, etc.) Builds on previous/existing LCCC research or continues prior phase trial completed here _____

Academic Credit: Low chance of authorship Likely authorship, UNC PI first or last author

Likely authorship, UNC PI will NOT be first or last author

Anticipated location for lymphodepletion/ conditioning (check all that apply): Inpatient Outpatient

Anticipated location for product infusion (check all that apply): Inpatient Outpatient

How is the product collected: Apheresis Whole blood Surgical procedure

Other services expected to be involved: _____

Any additional comments (feel free to elaborate about unique features to consider, etc. – both from patient needs and scientific interest, etc.):

Submitted by: _____ Date: _____

Please contact Natalie Grover, MD (Natalie_grover@med.unc.edu) with any questions about completing this form.

Received _____ Date: _____

Member of the Cellular Therapy Vetting committee

For Cellular Therapy Vetting Committee:

Beneficial for CT POD and LCCC to be able to offer this trial: No Yes, reason:

Impact on Study Coordinators: _____

Impact on Data Team: _____

Impact to QM team (additional audits): _____

Additional policies or Standard Operating Procedures required: No Yes

Impact to pharmacy: _____

Impact to Outpatient nursing: _____

Impact to Inpatient nursing: _____

Impact to BMTCTP APP: _____

Training that will be required of Nursing and APP: _____

Impact to Regulatory Team: _____

Impact to Apheresis: _____

Impact to HPC: _____

Impact to ACT Facility: _____

If LCCC IIT: Potential for multi-center trial: : No Yes

If yes, potential for shipping manufactured products externally: No Yes

Any additional impacts to consider: _____

Overall impression: _____

Move forward with offering this trial: No Yes

Comments: _____

Information reviewed by committee and decision made (date): _____

Committee member: _____ Date: _____

PI informed of decision: No Yes, date: _____