New Commercial CAR T Cell, TIL or Gene Therapy Product

To be completed and submitted to the BMTCTP Vetting Committee

Name of product ____

☐ *CAR – Target:* ____________________ ☐ TCR- HLA specificity: ____________________

☐ *Gene Therapy Target*: ____________________ ☐ *TIL*

☐ *Other:* ____

Manufacturer: ____________________ *Principal physician group:* ____________________

Disease(s) to be treated: ____

Patients impacted: ☐ Adults ☐ Pediatrics

Competing investigator initiated or sponsored trials: ☐ No ☐ Yes, ____________________

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Competing commercial products: ☐ No ☐ Yes, ____________________

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Anticipated number of patients to be treated each year with this product: ____________________

How does this therapy benefit the intended patient population and/or program? ____________________

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Please provide or list one key reference: ____

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

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

Required initial post infusion follow-up schedule, if known: ____________________

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How is the product collected: ☐ Apheresis ☐ Whole blood ☐ Surgical procedure

How is the product shipped to manufacturer: ☐ Fresh ☐ Cryopreserved

Other services expected to be involved: ____

____

Any additional comments: ____

____

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Submitted by: ____ *Date:* ____________

Please contact Natalie Grover, MD (natalie_grover@med.unc.edu) or Kim Kasow, DO (kkasow@med.unc.edu) with questions regarding completion of this form.

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Received by (member of the vetting committee): _________________________ *Date:*______________

For Cellular Therapy Vetting Committee:

Beneficial for BMTCTP to be able to offer this therapy: ☐ No ☐ Yes, ________________________________

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Impact on Data Management: ____

Will reporting to CIBMTR be required: ☐ No ☐ Yes ☐ Unknown at this time

Impact to QM team (additional audits): ____

Additional policies or Standard Operating Procedures required: ☐ No ☐ Yes

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____

REMS program 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 Cellular Therapy Coordinator: ____

Impact to Apheresis: ____

*Impact to HPC:*____

Any additional impacts to consider: ____

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Overall impression: ____

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____

Move forward with offering this product: ☐ No ☐ Yes

Comments: ____

____

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

Committee member: ____ Date: ________________

Primary disease physician informed of decision: ☐ No ☐ Yes, date: _______________________