

# Advanced Cell Therapies New Protocol Intake Form

General Information		
<b>Protocol Name/Title:</b>		
<b>Final Product Name &amp; Targeted Disease</b>		
<b>Final Product Type</b>	<input type="checkbox"/> CAR-T <input type="checkbox"/> CAR-NK <input type="checkbox"/> Cell Bank	<input type="checkbox"/> Other (Specify): _____
<b>Starting Materials (Source)</b>	<input type="checkbox"/> Autologous cells <input type="checkbox"/> Allogenic cells	<input type="checkbox"/> Other (Specify): _____
	<input type="checkbox"/> Apheresis <input type="checkbox"/> Bone Marrow <input type="checkbox"/> iPSC Bank <input type="checkbox"/> Cord Blood	
<b>Genetic Components</b>	<input type="checkbox"/> Lentiviral vector <input type="checkbox"/> Retroviral Vector <input type="checkbox"/> mRNA	<input type="checkbox"/> Other (Specify): _____
<b>Individual completing intake form</b>	<input type="checkbox"/> Sponsor Project Manager <input type="checkbox"/> Clinical Director <input type="checkbox"/> Institute Head	<input type="checkbox"/> Principal Investigator <input type="checkbox"/> Co-Investigator <input type="checkbox"/> Other (Specify): _____

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IND/ Study Information		
<b>Pre-Clinical/Clinical Trial Sponsor:</b>	<input type="checkbox"/> Institute/Hospital Sponsor _____ <input type="checkbox"/> Industry Sponsor: _____	
<b>Pre-Clinical/Clinical Trial phase (check all that apply):</b>	<input type="checkbox"/> Phase I <input type="checkbox"/> Phase II <input type="checkbox"/> Phase I/II	<input type="checkbox"/> Technology Transfer <input type="checkbox"/> Scale Up <input type="checkbox"/> Other: _____
<b>Current IRB status:</b> (IRB: Institutional Review Board)	<input type="checkbox"/> Pre-IRB <input type="checkbox"/> IRB-Submitted <input type="checkbox"/> IRB- Approved	
<b>Current FDA status:</b> (IND: Investigational New Drug)	<input type="checkbox"/> Pre-IND <input type="checkbox"/> IND-Submitted <input type="checkbox"/> IND Approved <input type="checkbox"/> Other: _____ IND Number: _____	
<b>ClinicalTrials.gov identifier or NCT # (if applicable):</b> _____		
<b>Trial Information</b>	Total expected number of participants: _____ Expected enrollment rate (Per Month/Year): _____ <input type="checkbox"/> Single-site <input type="checkbox"/> Multi-site : _____ Dose Escalation: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable Other (list): _____	
<b>Items to include with this request (if applicable):</b>	<input type="checkbox"/> Draft of manufacturing protocol <input type="checkbox"/> Technology Transfer Protocol <input type="checkbox"/> CMC section	<input type="checkbox"/> COA -Release Test Requirements Test Methods List if known: _____ <input type="checkbox"/> Clinical Trial Protocol <input type="checkbox"/> Manual of Procedures (MOP) <input type="checkbox"/> Vector Certification/COA <input type="checkbox"/> Vector sequence (IBC required) <input type="checkbox"/> Vector Map (IBC required) <input type="checkbox"/> IPSC Certification/COA

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IND/ Study Information	
<b>Requested Trial start and end Timeline</b>	<p>Trial Start/ end date: _____</p> <p>Tech Transfer target timeline: _____</p> <p>Process Development target timeline: _____</p> <p>GMP Manufacturing target timeline: _____</p>
<b>Trial Funding Source</b>	<p>Trial Funding secured (funding source name): _____</p> <p>Applied for funding (funding source name): _____</p> <p>Institute funding (Cost center/budget number): _____</p> <p>Other: _____</p>
<b>Services being requested</b> <i>(check all that apply)</i>	<p><input type="checkbox"/> Operational support</p> <p><input type="checkbox"/> Apheresis Collection</p> <p><input type="checkbox"/> Process Development</p> <p><input type="checkbox"/> Manufacturing support</p> <p><input type="checkbox"/> Assay Development</p> <p><input type="checkbox"/> CMC: Chemistry Manufacturing &amp; Controls</p> <p><input type="checkbox"/> Development methods and data summary (experimental design + data)</p>
<b>List of specialized equipment/instrumentation needed</b> <i>(complete if applicable)</i>	

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CONTACT INFORMATION (Complete applicable sections)	
<b>Project Manger</b>	Name: _____ Department: _____ Institute/ University: _____ Phone: _____ Email: _____
<b>Principle Investigator</b>	Name: _____ Department: _____ Institute/ University: _____ Phone: _____ Email: _____
<b>Business Contact</b>	Name: _____ Department: _____ Institute/ University: _____ Phone: _____ Email: _____

**Send completed form to: [srivase@ucmail.uc.edu](mailto:srivase@ucmail.uc.edu) or [CELLTHER@UCMAIL.UC.EDU](mailto:CELLTHER@UCMAIL.UC.EDU)**

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**Internal Notes (For Internal Use Only):**

**Business Requirements**  
*(check all that apply)*

- ☐ Material Transfer Agreement (MTA)
- ☐ Non-disclosure agreement (NDA)
- ☐ Individual Project Scope (IPS)
- ☐ Master Service Agreement (MSA)
- ☐ CDA- Confidentiality Agreement
- ☐ QAA-Quality Assurance Agreement
- ☐ Letters of cross-reference to IND or DMF

**Initial Review Person/Date:**

**Comments/Notes:**