Investigator Sponsored Trial Grant Application

Investigator Information	
Submitted by *(Name/Title)*:	
Affiliation/Institution:	
Address *(Include Country)*:	
Phone:	Email Address:
Medical License Number:	Medical License Expiration Date:
Description of Relevant Research Experience:	

Secondary Contact *(optional)*	
Name/Title:	
Affiliation/Institution:	
Address *(Include Country)*:	
Phone:	Email Address:

Study Protocol
Please complete the following section even if you plan to attach study protocol. Feel free to "cut and paste" from existing protocol
Proposal Title:
Scientific/Medical Rationale *(Objective)*:
Hypothesis:

Study Design *(include specifics on treatment arms, dosage regimens and rational for inclusion of placebo, if used)*:

Patient Population *(include description, number of patients, expected enrollment period, how the study population could benefit from the results of the research)*:

Primary and Secondary Endpoints *(If any additional endpoint, please include here. For patient outcome measures, please describe means of data collection, i.e. mail, phone, office visit)*:

Inclusion Criteria:

Exclusion Criteria:

Study Procedures *(include number of patient visits and evaluations occurring at each visit)*:

Safety Endpoints *(Please provide Safety Reporting Plan)*:

1. Please specify which individual(s) would be responsible for gathering information related to adverse events.
2. Please outline the plan to communicate adverse events to Vericel Pharmacovigilance (https://www.vcel.com/adverse-events-reporting/).
3. Please describe the process to report adverse events, as appropriate, to regulatory bodies, institutional review board(s), and/or investigators.

Statistical Analysis Plan *(if applicable)*:

Study Results *(include expected results and how they will be reported)*:

Study Timeframes	
Milestone:	Estimated Duration *(in months)*:
Time to IRB approval:	
IRB approval to the first patient visit:	
First patient in to last patient in (enrollment period):	
Last patient visit to data analysis:	
Data analysis to final study report:	

Protection of Human Subjects & Other Regulatory Considerations

Informed Consent Procedure *(include information on the manner in which consent is obtained and adherence to applicable regulations)*:

Patient Authorization *(include information on how patient authorization for disclosure of personal health information will be obtained)*:

IRB/IEC Approval *(include information about the IRB/IEC, confirming composition and mechanisms for provision of approval are consistent with CFR, ICH and local, regional, and national guidelines and that all necessary IRB/IEC approval will be obtained in connection with the proposed research)*:

Submission to Government Agency *(if applicable, describe regulatory strategy including type of submission)*:

Materials and/or Services Requested

Support Services:

Funding Requested

Total Funding Requested *(include LOA and itemized budget items from educational grant application following "Funding Requested section")*:

Grant Attachments *(to be completed by grant applicant)*

☐ Letter of request *(please include signed copy on organizational letterhead)*

☐ Itemized budget

I understand and agree to report all serious adverse events as required by regulatory authorities.
I verify by signature below that the above statements are true and that I am in good standing with all regulatory authorities:

Signature:	Printed Name:	Date: