IPEA Application

Treating Physician/Institution Contact Information

- Name of requesting physician: _____
- Name of institution (if applicable): _____
- Physician State of licensure and board license #: _____
- Physician phone number: _____
- Physician email: _____
- Physician and/or institution address (anticipated location of drug supply):
  _____
- Treating physician experience with Replimune investigational agents and/or relevant experience with administering intratumoral therapies:
  - Participation in REPL Clinical Trials (please report):
    _____
  - Experience with other intratumoral therapies:
    _____

IPEA Proposal

(Note: do not submit identifiable patient information or other personally identifiable information)

- Patient Gender Male ☐ Female ☐
- Patient Date of Birth: Click or tap to enter a date.

Patient medical history.

- Patient performance status: _____
  - Primary Diagnosis (Including date): _____
- Prior anti-cancer treatments received to date (Dates and duration):
  - A. Treatment:_____
    - From: _____ To: _____ Outcome: _____
  - B. Treatment:
    - From: _____ To: _____ Outcome: _____
  - C. Treatment: _____
    - From: _____ To: _____ Outcome: _____
  - D. Treatment: _____
    - From: _____ To: _____ Outcome: _____
  - E. Treatment: _____
    - From: _____ To: _____ Outcome: _____

- Concurrent non-oncology related medical conditions, procedures, or therapies of significance
  Click or tap here to enter text.

- Description of patient current disease/condition (please specify why the patient does not qualify for any of the company's (or other) ongoing clinical trials):
  Click or tap here to enter text.

  ☐ Check box if additional information attached

- Name of investigational drug being requested: ☐ RP1

- Description of the proposed treatment plan, including dose, duration, and lesion(s) to be injected:
  Click or tap here to enter text.

  ☐ Check box if additional information attached

Physician Attestation

Individual Patient Expanded Access

Physician Attestation, General Terms & Conditions

A. I am a physician duly licensed and authorized to practice medicine in the jurisdiction where the investigational drug(s) will be administered (please provide a copy of your CV and medical license).
B. I attest that treatments to this particular patient's disease have been exhausted and the patient is no longer responsive to, or able to tolerate, existing therapies and there are currently no other viable therapy options, including participation in ongoing relevant clinical trials.
C. I attest that the patient does not qualify for any of Replimune's current clinical trials.
D. I acknowledge and agree that the investigational drug(s) will be supplied solely for use by the patient who is the subject of this request and for no other purpose.
E. I attest that the investigational drug(s) will only be used under my direct supervision and will be stored under climate and control conditions specified by Replimune.
F. I agree that I, not Replimune, am and will remain responsible for all regulatory obligations associated with this request and my patient's use of the investigational drug(s).
G. I acknowledge that Replimune and I, or my institution, need to mutually agree on the terms and condition of a clinical trial agreement, ensuring Replimune the timely right to all information from my treatment using the investigational drug(s), including but not limited to safety and efficacy data, as well as, intellectual property terms and other customary rights and obligations.
H. I agree that, prior to the first administration of investigational drug, I will inform my patient of the risks associated with the investigational drug(s), including that it has not been approved for marketing in this country, and will obtain his/her informed consent (or that of his/her legally acceptable representative) in accordance with applicable laws and regulations.
I. I will ensure that the informed consent authorizes the appropriate collection of my patient's health information and transfer to and use by Replimune, its collaborators, service providers and others in connection with the development and commercialization of the investigational drug(s).

J. I acknowledge that I, not Replimune, am and shall remain responsible for maintaining my patient's identifiable patient information or other personally identifiable information and that such shall not be provided to Replimune unless necessary for a qualifying regulatory purpose.
K. I will obtain any required approvals from and/or make any required notifications to governmental authorities, institutional review board, independent ethics committee or the like, applicable to the use of the investigational drug(s) for my patient and will notify Replimune immediately if any such approvals are withdrawn, suspended or revoked. I acknowledge that Replimune will not supply any investigational drug(s) until, among other things, documentation of such approvals or notices have been provided.
L. I will further provide Replimune with copies of any material correspondence with any such governmental authorities, institutional review board(s), independent ethics committee(s) or the like, relating to the use of the investigational drug(s) for my patient.
M. I agree to report, via email to saeintake@fortrea.com within the below detailed timelines, all serious adverse events associated with use of the investigational drug(s), regardless of causality, by providing a copy of the original CIOMS or MedWatch form submitted to the applicable regulatory authority:
    a. All initial fatal or life-threatening suspected unexpected serious adverse reactions: within 1 business day from the date of occurrence
    b. All follow-up fatal or life-threatening suspected unexpected serious adverse reactions: within 10 calendar days from the date of occurrence
    c. All non-fatal or non-life-threatening serious adverse drug reactions: within 10 calendar days from the date of occurrence
    d. Pregnancy reports (inclusive of partner pregnancy): within 10 calendar days from report of a positive test
    e. All other serious adverse events: within 15 calendar days from the date of occurrence
N. I will maintain the confidentiality of information provided about the investigational drug(s) and I will only disclose or disseminate such information as required by law or regulation or as otherwise authorized in advanced written permission by Replimune.
O. I agree that Replimune may use any and all of the data and results generated from or related to the administration of the investigational drug(s) for any purpose in accordance with applicable laws, and I hereby agree to and do assign all resulting or investigational drug related patent or other intellectual property rights to Replimune.
P. I will inform Replimune when my patient discontinues treatment with the requested investigational drug(s). I acknowledge and agree that Replimune may discontinue supply of an investigational drug if Replimune terminates development of such investigational drug or it becomes approved for use in this country.
Q. I am familiar with, understand, and agree to comply with all applicable laws and regulations relating to the pre-approval use of investigational drugs.
R. I certify with my signature directly below, that I have read, understand, and accept these terms and conditions for access to Replimune's IPEA program.

Physician Name: _____	
Physician Signature:	Date: Click or tap to enter a date.