



Project Proposal Form: Cancer Immunotherapy Track

*If you have been **invited** to submit a full proposal to the Focused Ultrasound Surgery Foundation (FUSF) Research Awards Program, please complete this form and submit it electronically via the Foundation's online submission system located at <http://fusf-rap.edmgr.com>. Please be sure to provide all information requested. Incomplete submissions will be returned to the applicants for revision.*

Part A – Cover Page

- I. Project Title:**
- II. Principal Investigator:**
 - Degree & Position:
 - Name of Institution:
 - Email:
 - Phone:
- III. Co-Investigators (Please limit the number of co-investigators to five (5)):**
 - Co-Investigator 1:**
 - Degree & Position:
 - Name of institution:
 - Co-Investigator 2:**
 - Degree & Position:
 - Name of institution:
 - Co-Investigator 3:**
 - Degree & Position:
 - Name of institution:
 - Co-Investigator 4:**
 - Degree & Position:
 - Name of institution:
 - Co-Investigator 5:**
 - Degree & Position:
 - Name of institution:
- IV. Total Project Budget (US dollars): \$**
- V. Total Funding Requested from FUSF (US dollars): \$**
- VI. Length of Proposed Funding Period (e.g., 1 year):**
- VII. Number of Animals or Patients Involved:**
- VIII. Focused Ultrasound System or Equipment Used:**

IX. Ultrasound Application(s) (*e.g., HIFU, histotripsy*) **and Bioeffect(s)** (*e.g., tissue destruction, immunomodulation*) **Utilized:**

X. Please provide a 50-100 word abstract (*i.e., a non-enabling description that may be posted on the Foundation's website if the proposal is funded*):

Part B – Research Proposal
- not to exceed 7 pages –

Please Note: if you would like to include figures or images as part of your application, please upload them as separate files into the foundation’s online submission system. Figures, images and literature citations will not be counted towards the total page limit.

I. Hypothesis:

II. Specific Aims:

III. Background & Significance:

IV. Statement of Work (*Please Include: total number of patients, anticipated enrollment rate, patient selection criteria (i.e., inclusion/exclusion criteria), as well as a detailed description of the investigational plan.*):

V. Please complete the following table of quarterly research goals:

Quarter	Research Goals
1	
2	
3	
4	

VI. Summary of measurable results:

VII. Please explain how the proposed project addresses the following questions, where applicable:

1. What are the comparative immune effects induced by different FUS modes? How do these compare to other therapies (i.e. radiation, cryoablation, RF ablation)?
2. How do FUS immune effects vary by tumor type?
3. What clinical disease targets are ideal for FUS + immunotherapy combinations?
4. How can we improve/optimize FUS treatments for immunomodulation (i.e. drugs combinations, partial vs. total tumor treatment, timing of treatments)?
5. What metrics can be used to predict clinical success? (T cell ratios, etc) Can blood samples in the absence of biopsies reliably predict response?

VIII. Does your statement of work align with our [preclinical](#) or [clinical](#) guidelines for immune assessment following FUS treatment? If not, please provide a rationale.

Part C – Budget & Budget Justification

Please **attach** a budget and budget justification detailing the direct cost (in US dollars) of the entire project, including salaries, costs for laboratory materials, contracted services, etc.

Please note: The Foundation will not pay for institutional overhead or indirect costs. The budget and budget justification should be uploaded directly into the Foundation's online submission system and should **not** be incorporated into the application form itself.

Part D – Biographical Sketches

Please **attach** a biographical sketch for the principal investigator and for each of the co-investigators listed in Part A of the application form. Whenever possible, biographical sketches should be in NIH format.

Biographical sketches should be uploaded directly into the Foundation's online submission system and should **not** be incorporated into the application form itself.

Part E – Debarment

Copies of all FDA Notices of Violation on Form 483 and Warning Letters naming or addressed to any investigator identified in the application, together with all written responses. Each applicant must certify that no investigator identified in the Application is on the FDA's debarment list.