Focused Ultrasound Foundation

Research Funding Applicant Guide

02/09/2026

V1.2

About the Focused Ultrasound Foundation

The Focused Ultrasound (FUS) Foundation's mission is to accelerate the development of new applications of focused ultrasound and its widespread adoption as a standard of care. This mission is both **patient focused** and **time sensitive**. To accomplish this mission, the FUS Foundation funds milestone driven, proof-of-concept projects that may be considered "high risk" in that there is a high probability of a null hypothesis.

Applying for funding

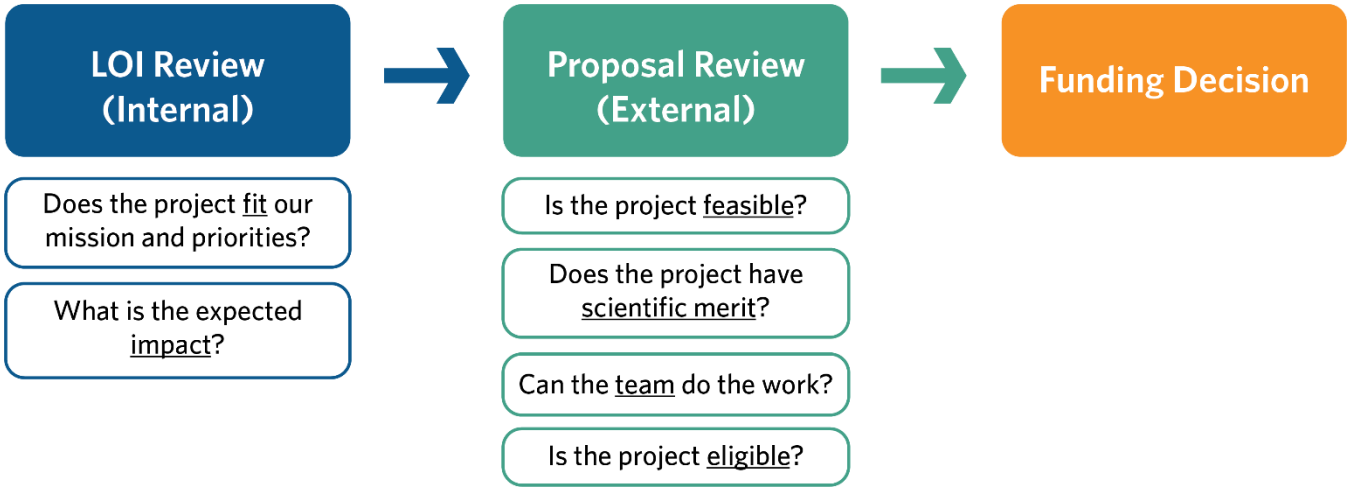

Figure 1: Proposal Evaluation Process. The top boxes show the steps of proposal evaluation. The boxes beneath each step highlight the questions addressed by a given step.

Evaluation Process

The FUS Foundation uses a two-stage process to evaluate research proposals (Figure 1).

The first stage of proposal evaluation begins when the principal investigator (PI) submits a letter of intent (LOI). The LOI is evaluated for fit with the FUS Foundation mission and research priorities. After reviewing the LOI, the FUS Foundation notifies the PI if they are invited to submit a full proposal.

The second stage of proposal evaluation begins when the PI submits an invited full proposal. The PI has 90 days to submit after receiving an invitation for proposal. The proposal is evaluated on its feasibility, scientific merit, team, and eligibility. During this stage, the FUS Foundation evaluates the proposal in more detail and gives the PI the opportunity to iterate on their proposal to make it stronger through reviewer feedback. The full proposal is peer reviewed externally by scientific and clinical experts, the review results are shared during a Research Funding Meeting, and a decision is made (fund, revise, reject). Research Funding Meetings for proposals occur every 2 weeks. If a decision to fund is made, the proposal enters the post-award phase where contracting begins. If a decision to revise is made, the PI is given the opportunity to address reviewer comments, and the revised proposal is evaluated. If a decision to reject is made, the PI is notified of this decision and provided with the reviewer comments. All funding decisions are at the sole discretion of the FUS Foundation funding committee.

If selected for a Research Award, the FUS Foundation Program Manager for the relevant Research Program or the FUS Foundation Contract team will work with the PI and their institution to put a Funding Agreement and associated exhibits in place. See *Funding Agreements* for more details.

Research Priorities

Eligibility for awards is determined by our research priorities as defined by the following criteria:

1. **Technology**: The FUS Foundation only funds projects involving the use of non-invasive image-guided focused ultrasound to treat disease
2. **Research Stage**: The FUS Foundation supports preclinical translational research studies and clinical trials. Research funding is prioritized for:
    a. Preclinical translational studies, including veterinary medicine studies, with an emphasis on translational proof of concept laboratory studies with the goal of supporting clinical trials
    b. Clinical trials for first-in-human and other innovative clinical trials
3. **Mechanisms of Action**: The FUS Foundation prioritizes funding for research on:
    a. Immunomodulation
    b. Neuromodulation
    c. Gene and cell therapy
    d. Drug delivery (including Blood Brain Barrier opening)
    e. Sonodynamic therapy
4. **Clinical Indications**: The FUS Foundation prioritizes funding for research in the fields of oncology and neurodegenerative disease. Current priorities include:
    a. Neurodegenerative disease: Alzheimer's disease, Parkinson's disease, Huntington's disease, amyotrophic lateral sclerosis (ALS), dementia
    b. Cancer and cancer immunotherapy: glioblastoma (GBM), diffuse intrinsic pontine glioma (DIPG), diffuse midline glioma (DMG), pancreatic cancer, breast cancer, and metastatic cancer

Research Award Types

The FUS Foundation offers two types of Research Awards through a competitive peer-reviewed application process.

Preclinical Research Awards: The FUS Foundation funds investigator-initiated preclinical or early-stage research projects that can lead to treatments for disease. In addition to preclinical studies focused on human disease, we fund veterinary comparative medicine trials that will aid in the adoption of focused ultrasound therapies for human use.

Clinical Research Awards: The FUS Foundation funds first-in-human and other innovative clinical trials involving the use of image-guided focused ultrasound to treat diseases.

Research Programs

Awards are assigned to one of the following programs:

Brain

Body

Cancer Immunotherapy

Gene and Cell Therapy

Neurodegenerative

Veterinary

Eligibility

To be eligible for FUS Foundation funding, the applicant and their proposal must meet the following criteria:

- The project must involve the use of non-invasive image-guided focused ultrasound to treat disease.
- PI must be in a tenure track faculty position (academia) or a full-time employee (industry)
    - Postdocs and fellows are eligible for awards but must have a Co-PI that is in a tenure track faculty position.
    - Full-time, non-tenure track faculty may be eligible but must have a letter from their institution stating that they are eligible to act as a PI.
- The proposal must be for a milestone driven research project. This applies to both academic and industry research projects.
- Companies may submit proposals to the FUS Foundation, but FUS Foundation funding is not non-dilutive. Read more about this in the *Intellectual Property, Royalty Agreement, and SAFE* section.

Where to Apply

The FUS Foundation accepts applications for funding through the ProposalCentral platform. Instructions for creating a profile and using ProposalCentral are provided on the ProposalCentral website. Once a profile is created, the principal investigator can submit an LOI to the FUS Foundation for consideration.

LOIs are accepted at any time for all Research Award Types and Research Programs. FUS Foundation staff strive to review LOIs within two weeks of receipt. Following LOI approval, proposal submissions for all programs are accepted on a rolling basis. Funding decisions are completed on a rolling schedule as well, with decisions formed in a timely fashion.

Letter of Intent (LOI)

The LOI is a series of questions of the proposed research project. LOIs are assessed for their fit to the FUS Foundation mission (determined by our Research Priorities) and potential impact. Exceptional opportunities to treat disease that are outside of the Research Priorities will be considered if there is the potential for rapid clinical translation and immense patient impact. The LOI questions are included in the section *LOI Questions*. Each question in the LOI has a character limit and no attachments can be provided with the LOI.

Full Proposal

The content and forms in a full proposal vary by Research Award Type (Preclinical vs Clinical) and Research Program (Cancer Immunotherapy vs Veterinary vs Other Programs).

Project Length

The FUS Foundation mission is both **patient focused** and **time sensitive**. As a result, the FUS Foundation typically funds projects that are short in duration (usually 1 year for Preclinical Research Awards). This requires that projects be sufficiently small and focused in scope to allow for the research to be completed on time.

Project Narrative

The project narrative for a Preclinical Research Award describes the unmet need, solution, proposed research project, its impact, and its clinical translation. A project narrative template is provided below that includes questions that PIs may wish to address in their proposal. The project narrative is limited to 7 pages including figures and excluding the reference list which may be provided separately.

For Clinical Research Awards, the PI **MUST** submit a clinical trial protocol drafted for IRB, FDA, or other regulatory purposes. It is recommended that the PI include a cover letter describing the project impact and any relevant background information with the protocol. In addition, the Clinical Research Awards application in ProposalCentral includes questions about how recruitment will be performed for the study.

General Project Narrative Template: Use this template for Preclinical Research Awards proposals that are not in the cancer immunotherapy or veterinary spaces.

Cancer Immunotherapy Project Narrative Template: Use this template for Preclinical Research Award proposals using FUS to induce or stimulate an immune response, either alone or in combination with an immunotherapeutic.

Veterinary Project Narrative Template: Use this template for veterinary medicine proposals.

Budget

Submitted budgets must follow the FUS Foundation's requirements as outlined below and be in the FUS Foundation format. Preclinical and Clinical Research Awards have different budget forms and templates for both are provided/linked (above). Preclinical Research Awards provide a budget of labor, materials, and services for the entire project. Clinical Research Awards provide a budget detailing the services and labor needed on a per patient basis. Preclinical Research Awards are typically up to $150,000 and 1-year duration.

Allowable costs

The following costs are permitted:

- Salary (plus benefits) for the PI, Co-Investigators (Co-I), and any scientific and/or clinical research personnel directly involved in the conduct of the project, limited by the current NIH annual salary cap ($225,700 in 2025) and pro-rated by percent effort of involved personnel. Salary costs in Clinical Research Awards must be divided into the budget on a per patient/per visit basis.
- Consumable supplies
- Animal and vivarium costs
- Costs associated with data collection and analysis
- Costs associated with sample storage
- Central lab fees
- IRB review fees
- Travel costs incurred either as a direct result of conducting the research or for the purpose of presenting the results of the project at scientific or medical meetings. Please specify the meetings where you expect to present the results.
- Data curation for inclusion in data collaboratives

Unallowable costs

The following costs are not permitted:

- Indirect costs
- Overhead
- Capital equipment
- Product development

- Tuition
- Protocol development labor

Publication Costs

Additional fees for open access publication of a manuscript are reimbursable but should not be included in the budget.

Other budget requirements

- Budgets must be submitted using the FUS Foundation's Budget Template.
- Budget items totaling > $5,000 must be detailed on a per unit basis.
- In the case of Clinical Research Award applications, the study budget is withheld from the peer-review materials.

Project Co-Funding

It is considered advantageous if institutional/departmental support and/or support from other sources—such as the NIH, foundations, or other philanthropic organizations—is available for the research project for which FUS Foundation funding is requested.

However, the FUS Foundation will not award funds to duplicate any work that is being supported by other funding agencies. Budgetary overlap is not permitted; however, scientific overlap will be evaluated on an individual basis. In cases of significant scientific overlap, a successful applicant will have the option to choose between the FUS Foundation Research Award and that of the other organization.

Preclinical Budget Template

Clinical Budget Template

Biosketch/CV

Biosketches or CVs should be provided for all investigators (PI and Co-Is). A biosketch or CV is required for research staff (e.g., graduate students, laboratory technicians) with a commitment of more than 5% to the project.

Reference list

A list of references from the Project Narrative may be included as a separate document.

Revisions

If invited to submit a revised proposal, be sure to track or list changes and/or a rebuttal against each of the points raised in the reviewers' comments. Revisions must be submitted within 90 days of the invitation through the ProposalCentral platform.

Funding Agreements

Once selected for a FUS Foundation Research Award, the FUS Foundation contracting team and the FUS Foundation Project Manager responsible for your Research Award will help put a Funding Agreement in place and will then track, review, and authorize payment based on completion of research milestones or patient treatment. In general, the first installment of the award will be paid once the CRFA/RFA is fully executed by all parties.

For all Funding Agreements, once all exhibits are approved by the FUS Foundation and the principal investigator, the FUS Foundation will compile a full Funding Agreement and send via e-mail to the PI and their institutional Grants and Contracts department for review. Any changes to the template language will need to be discussed with and approved by the FUS Foundation Director of Operations and FUS Foundation legal counsel.

Research Funding Agreement (RFA)

Preclinical Research Awards use a Research Funding Agreement (RFA). FUS Foundation RFAs are paid based on the receipt and approval of deliverables, each of which is associated with a research milestone. These are clearly laid out in an exhibit to the RFA, and thus the first activity following notification of selection for a Research Award is establishing the Schedule of Milestones and Deliverables exhibit to the funding agreement. The Project Manager assigned to your award will work directly with the project PI to come to a mutually agreed schedule of milestones and deliverables.

Research Funding Agreement Template: https://fusfoundation.org/pdf/research-funding-agreement-template

Statement of Work

Typically, the Statement of Work is drawn from the submitted proposal. Once the FUS Foundation and Institution mutually agree upon a Statement of Work for the study this document will be included as an exhibit in the Research Funding Agreement. **The Statement of Work is a binding agreement of what work will be completed during the project.** Any new activities, budget changes, or variations in the Statement of Work require a change request and an amended Statement of Work to be approved and signed by both the FUS Foundation and the Institution.

Deliverables & Payments

Preclinical Research Awards from the FUS Foundation are milestone driven. Milestones, as identified in the proposal, are key achievements towards the project's goals. To verify completion of a milestone, we will track deliverables. A deliverable must be a verifiable work product that relates to the accompanying milestone.

Milestones and deliverables are documented in Exhibit C - The Schedule of Milestones and Deliverables. The Project Manager (PM) for the project will prepare a list of deliverables and proposed payments for those deliverables that will be included in the Research Funding Agreement as Exhibit C. The PI will review Exhibit C and provide edits. Once agreed upon, the Project Manager will share Exhibit C with the FUS Foundation Contracting team to include it in the Research Funding Agreement. A final report and submission of a manuscript for publication are typically included in the project deliverables. Reports and manuscripts for publication must comply with relevant reporting requirements (see *Reporting Guidelines & Other Requirements*).

Payment is made when a deliverable is submitted and accepted by the FUS Foundation Project Manager. Acceptance of a deliverable is contingent upon the completion of the work as outlined in the Statement of Work, not the results of that work. As an example, if an experiment is completed as described in the Statement of Work and the associated deliverable is submitted as written in the Schedule of Milestones and Deliverables but the results are negative, the FUS Foundation will release payment for the deliverable.

Clinical Research Funding Agreement (CRFA)

Clinical Research Awards use a Clinical Research Funding Agreement (CRFA). CRFAs are paid and invoiced based on patient visits as written in the Clinical Budget. Payment terms are clearly defined in a Study Budget exhibit to the CRFA, covering startup costs, per subject payments, and any additional expenses necessary for the study. In addition, the Study Protocol will be included as an exhibit to the CRFA. Clinical trials must also be registered at clinicaltrials.gov.

Clinical Research Funding Agreement Template: https://fusfoundation.org/pdf/clinical-research-funding-agreement-template

Intellectual Property, Royalty Agreement, and SAFE

All inventions/discoveries, whether or not patentable, made or developed in the course of performing the Study or utilizing the Study Data, must be disclosed to the FUS Foundation. Should that intellectual property be licensed for commercialization the FUS Foundation requests a portion of the income be paid to the FUS Foundation. For an investigator-initiated study, the FUS Foundation requests 20% of the net annual income from the intellectual property, up to five times the initial research funding award be paid to the FUS Foundation. For FUS Foundation initiated studies, where the FUS Foundation creates a Statement of Work and solicits investigators to perform the research, the FUS Foundation requests 80% of the net annual income from the intellectual property with no cap on the amount to be paid to the FUS Foundation. This is a non-negotiable term of our funding. Such payments are further defined using customary terms in the FUS Foundation Royalty Agreement.

When the FUS Foundation makes an award to a company, the funding is not non-dilutive. If the company is pre-revenue our preferred funding mechanism is a Simple Agreement for Future Equity (SAFE). Our template is based on the 5-page Y Combinator template. Only one number needs to be negotiated – the valuation cap. For later-stage companies we generally propose a royalty agreement. Terms need to be negotiated on a case-by-case basis.

FUS Foundation Royalty Agreement Template: https://fusfoundation.org/pdf/royalty-agreement-template

Y Combinator SAFE Template: https://www.ycombinator.com/documents/

Organizational Assurances

Before releasing any funds for approved projects, the FUS Foundation requires proof of Compliance with Human Subjects and Animal Care Assurance committees.

In the cases of clinical trials with human subjects, we require proof of compliance with an Internal Review Board (or European/Asian equivalent) along with a copy of the **approved clinical trial protocol**. Please inform the FUS Foundation if any filings are made to the FDA or other regulatory agency, including but not limited to an Investigational Device Exemption or Investigational New Drug application. Patient informed consent must include mention of any data sharing plan.

Reporting Guidelines & Other Requirements

All reports and publications from research supported by the FUS Foundation must adhere to relevant guidelines published by the FUS Foundation. Currently, the FUS Foundation provides guidelines for FUS treatment parameter reporting and Immune Analysis during FUS research.

Guidelines for Immune Analysis During Focused Ultrasound Research

Local focused ultrasound treatment of neoplastic lesions that induces or enhances a systemic anticancer immune response could provide major therapeutic benefits to patients with cancer.

Monitoring the characteristics and temporal evolution of the immune response will provide key information needed to maximize the effectiveness of focused ultrasound treatment. This information is necessary to optimize focused ultrasound treatment parameters while further increasing the likelihood of therapeutic success through combination with immunotherapeutic agents or chemotherapies known to have immunostimulatory effects.

The guidelines, both for preclinical and clinical studies, include suggestions for analysis routes and assays. We emphasize the need to run a few very pointed assays/analyses first, before storing the remaining samples for later analysis.

Immune Analysis Guidelines: https://jitc.bmj.com/content/11/11/e007455

Padilla F, Foley J, Timbie K, *et al* Guidelines for immunological analyses following focused ultrasound treatment. *Journal for ImmunoTherapy of Cancer* 2023;**11:**e007455. doi: 10.1136/jitc-2023-007455

Guidelines for Focused Ultrasound Treatment Reporting

The community has identified the need for a set of guidelines to establish key parameters to report and the associated measurement methodologies to use for focused ultrasound research. The guidelines outlined in this document aim to fulfill three main objectives:

- To ensure consistency in the reporting of focused ultrasound treatment parameters, to allow cross-comparison of studies performed by different groups and/or with different systems.
- To provide guidelines for assessing and reporting bioeffects associated with different focused ultrasound treatment regimens, necessary for (1) cross-comparison of studies, (2) validation of therapeutic bioeffects.
- To provide guidelines for testing and calibration of the focused ultrasound systems and protocols.

The guidelines propose overall recommendations for important parameters to report; detailed methodologies for measuring/simulating focused ultrasound system and field parameters, detailed methodologies to assess bioeffects, DQA procedures for focused ultrasound equipment, and links to relevant standards and references.

Treatment Reporting Guidelines: https://cdn.fusfoundation.org/2024/06/11120020/FUSF-UMB-R1-Final-forDistribution.pdf

Padilla F & ter Haar G. Recommendations for Reporting Therapeutic Ultrasound Treatment Parameters. *Ultrasound in Medicine & Biology* 2022; **48**: 1299–1308. doi: https://doi.org/10.1016/j.ultrasmedbio.2022.03.001

Guidelines for Data Sharing

The FUS Foundation requires that research it funds be published with a Data Availability Statement, which specifies how data generated will be archived or made available to other researchers. The FUS Foundation reserves the right to request that funded researchers deposit their study data in a public repository or provide it to the FUS Foundation so that we may deposit it ourselves. For immuno-oncology projects, we require that researchers deposit data in our immuno-oncology repository.

The FUS Foundation advocates for open data practices and has created and maintains a data repository. The creation and maintenance of projects in the collection come at no cost for the investigators. Only immuno-oncology projects are required to deposit data in our immuno-

oncology repository currently, but other projects are welcome to deposit data in the FUS Foundation repository.

Our objective is to create an ecosystem of focused ultrasound data, providing researchers with the opportunity to access the source data to replicate, re-analyze, or support the development of their own projects or protocols.

These data will include source data, methodology, descriptions of experimental systems and their characterization, and details of any software used to process the results.

These guidelines provide information about data to be included, where the data should be stored, and how data should be presented.

FUS Foundation Data Sharing Guidelines:
https://www.fusfoundation.org/content/images/pdf/DRAFT-Recommendations-DataSharing-v7-Focused_Ultrasound_Foundation.pdf

Project Progress

Progress Reports (RFA only)

Once the RFA is fully executed by all parties, your Program Manager will share with the PI an updated Schedule of Milestones and Deliverables with actual dates. Your Project Manager will send an e-mail reminder a few weeks ahead of each deliverable deadline and will also be responsible for reviewing deliverables for scientific content and clarity. Any substantive questions regarding results or omissions in the deliverable must be addressed before the Program Manager can approve the next installment of the award.

Progress Report Template: https://www.fusfoundation.org/images/ProgressReportTemplate.pdf

Monthly Recruitment Updates (CRFA only)

Monthly recruitment updates are required as part of any Clinical Research Award. These do not apply to Preclinical Research Awards. Screening logs need to be completed monthly, in English and saved as a PDF. All completed logs should be sent to Robin Jones, Director of Clinical Trials Coordination.

Screening Log Template: https://www.fusfoundation.org/images/7Exhibit_F_-_FUSF_Screening_Log_-_REVISED_01_10_2017.pdf

Final Report

The penultimate deliverable on your project should be a comprehensive report in the format of a conference proceeding and should be uploaded directly to the FocUS archive or another public preprint server (e.g. bioRXiv) by the PI. This report will comply with relevant reporting guidelines. The FocUS Archive is hosted by the Center for Open Science (COS) and publicly indexed by way of Crossref. The purpose of this server is to ensure that final reports of FUS Foundation-funded research are available as quickly and broadly as possible. The FUS Foundation has the right to release the final report through the FocUS Archive 90 days after the report has been submitted if the work has not been submitted for publication.

Final Report Template: https://www.fusfoundation.org/images/FinalReportTemplate.pdf

FocUS Archive: https://osf.io/preprints/focusarchive

FocUS Archive upload instructions video: https://youtu.be/X72fqrvlDaI?si=YQUt3vyEXSxPjjv0

Publication

In most cases, one final payment is linked to the submission of a manuscript on the topic of your research project to a peer-reviewed journal. This deliverable is distinct from the Final Report. This publication must:

- Comply with the FUS Foundation's Guidelines for Focused Ultrasound Treatment Reporting
- Comply with the FUS Foundation's *Guidelines for Immune Analysis During Focused Ultrasound Research*
- Acknowledge FUS Foundation funding
- Be submitted to an open-access journal or submitted through the open-access option at a journal

Ongoing Responsibilities

For three years following the conclusion of the FUS Foundation Research Award, we require that you inform the FUS Foundation of any IP generated or licenses resulting from FUS Foundation funded work (this is also detailed in the CRFA/RFA). Additionally, we must be informed of any follow-on funding you earn based on data collected through your FUS Foundation-funded project. One of the strongest measures of success we have for projects is the ability of our PIs to receive follow-on funding. We also use this information to compute a leverage on initial investment figure for our philanthropic donors.

Program Specific Requirements

In addition to the above requirements, individual FUS Foundation programs have the following requirements.

Immuno-oncology

- Data must be deposited in the immuno-oncology repository we co-founded with COS (https://osf.io/collections/fusf/discover)
- Immune analysis reporting guidelines must be followed (https://jitc.bmj.com/content/11/11/e007455)

Other Policies

No Cost Extension (NCE)

The FUS Foundation's mission is time sensitive. As such, we work with our applicants to scope proof-of-concept projects that can be completed in a timely manner. No cost extensions can only be provided where there is clear justification. The FUS Foundation will consider no cost extensions on a case-by-case basis. A no cost extension request must be submitted by the project PI to the FUS Foundation Project Manager. No cost extensions are limited to twice the project length (e.g., if the project length is 1 year, the maximum no cost extension would be an additional year).

Artificial Intelligence (AI) policy

The FUS Foundation may enter application materials inFUSF approved generative AI systems. FUSF approved systems are systems where the data is protected by a service agreement with the provider and the model is not trained on the data.

FAQs

Q: Can patients apply to receive funding for Focused Ultrasound treatments?

A: No.

Q: Do you fund projects outside the United States?

A: Yes, we currently fund projects in over thirty different countries.

Q: Who are your reviewers?

A: Though anonymous, our reviewers are experts in focused ultrasound, engineering, and various medical and scientific specialties. Reviewers for each application are selected to have the most relevant areas of expertise.

Q: What are the FUS Foundation's current funding priorities?

A: See *Research Priorities*.

Q: I have an idea, but it does not fit into one of your categories. Will you still consider funding my project?

A: Yes, please email Joe Kilroy, PhD, at jkilroy@fusfoundation.org to discuss.

Q: Who is eligible for funding?

A: MD and PhD level scientists affiliated with a research institution are eligible to apply for funding. Post-doctoral researchers are encouraged to apply for funding but will need to list themselves as a co-investigator along with the lab principal investigator. Full-time employees at a company are also eligible to apply for funding.

Q: What types of projects do you fund?

A: See *Research Priorities* and *Research Award Types*.

Q: What is the timeline for an application? What are the submission deadlines?

A: LOIs are accepted on a rolling basis. FUS Foundation staff strive to review LOIs within two weeks of receipt. Following LOI approval, proposal submissions for all programs are accepted on a rolling basis within the 90-day period following invitation of the proposal. Funding decisions are completed on a rolling schedule as well. Submission is on a rolling basis, so there are no deadlines. See *Evaluation Process* for more information.

Q: Why are the terms different in this contract from the one that I previously received from FUS Foundation?

A: Our contract templates are reviewed annually and updated to reflect the best practices among health research funding organizations.

Q: Where do I submit my deliverables and project reports?

A: Please email your deliverables and project reports to your FUS Foundation Project Manager.

Q: How are funds/awards disbursed for Preclinical Research Awards?

A: Funds for Preclinical Research Awards are disbursed based on the submission of deliverables as detailed in your Research Funding Agreement. Preclinical Research Awards typically include a start-up payment when the Research Funding Agreement is signed and then additional payments upon acceptance of the agreed upon deliverables.

Q: How are funds/awards disbursed for Clinical Research Awards?

A: Funds for Clinical Research Awards are disbursed on a per patient treated basis as detailed in your Clinical Research Funding Agreement. In addition to per-patient treatment payments, there is typically a start-up payment when the Clinical Research Funding Agreement is signed and invoiceables that are paid through the course of the project.

Q: What will happen if the results of my project are negative? Will the FUS Foundation still provide payment?

A: The FUS Foundation pays for the completion of the work outlined in the Statement of Work. If the work is completed as outlined in the Statement of Work, the FUS Foundation will release payment for the deliverable. If results for an early deliverable are negative, the PI should discuss the remaining work with their FUS Foundation Project Manager to determine how to proceed with the project.

Q: Are there restrictions on what funds can be used for?

A: Yes. Allowable costs are listed in the Budget section above. If you have questions about restrictions, please contact Joe Kilroy, PhD, at jkilroy@fusfoundation.org to discuss.

Q: What is your IP policy for funding?

A: Our IP policy is detailed in the *Intellectual Property* section above.

Q: What is the FUS Foundation's Data Sharing Policy?

A: The FUS Foundation requires that research it funds be published with a Data Availability Statement, which specifies how data generated will be archived or made available to other researchers. The FUS Foundation reserves the right to request that funded researchers deposit their study data in a public repository or provide it to the FUS Foundation so that we may deposit it

ourselves. For immuno-oncology projects, we require that researchers deposit data in our immuno-oncology repository. Learn More.

Q: Do you provide funds to support the requirements for data conversion?

A: Data curation for inclusion in data collaboratives is an allowable cost. For more information on allowable costs, please see our *Budget* section above.

Q: Do you provide no cost extensions?

A: Our mission is time sensitive and as a result, no cost extensions can only be provided where there is a clear justification. The FUS Foundation will consider no cost extensions on a case-by-case basis. A no cost extension request must be submitted by the project PI to the FUS Foundation Project Manager.

Proposal Criteria Questions

As you prepare your proposal, please keep in mind the questions below. Some may not be applicable to your stage of development but will ultimately need to be addressed to successfully bring a treatment to the clinic.

Does this project align with a clinical need?

- Will this project result in a new treatment that meets a critical unmet clinical need?
- Will this project improve an existing treatment by making it safer, more effective, more convenient, more comfortable, more accessible, lower cost, and/or more rapid?
- Is this study exploratory/observational or hypothesis driven?

How will this project impact patients?

- Will this project materially increase the number of patients treated with focused ultrasound? How many?
- Will this project result in a new indication that can be reimbursed and widely available in 5 to 7 years?
- How long will it take to complete and how much will it cost until the study impacts patients?

How will this project be approved and reimbursed?

- Will this project facilitate regulatory approval or reimbursement?
- Will this project create new knowledge?
- How much will users be willing to pay for this new product or treatment?

What will the impact on the field of focused ultrasound be?

- Will this project have a profound impact on the field in terms of awareness amongst the public and medical communities?
- Will this project result in rapid presentation and publication of results?
- Will this project benefit one manufacturer or multiple?

Is there demand for this project?

- Where is the demand for this project coming from? Clinicians, scientists or patients?
- Are there donors interested in supporting this project?
- Are there co-funding sources such as related foundations, academic institutions or industry? Who?

How will this project translate into the clinic?

- If this project is related to mechanism of action, will it translate into a clinical indication (s) of unique value?
- How much time and effort will it take to translate the results of this project to the clinic, and by whom?
- Are there commercial organizations that will manufacture and distribute the product of this research? Who

IT'S ALL ABOUT THE PATIENTS

LOI Questions

The following fields and questions are included in the FUS Foundation LOI. Fields marked with * are required.

Project Title*
Total Project Budget (US dollars) *
Total Funding Requested from FUSF (US dollars) *
Proposed Start Date*
Length of Proposed Funding Period (years)*
Principal Investigator
ORCID iD:
ORCID Authorization:
Principal Investigator Contact Information*
Co-Investigator Contact Information
Applicant Institution*
Highest Degree(s)*
Position/Title*
Email*
Institution Name and Address*
Estimated study sample size*
Subject type
If other, please explain
Focused Ultrasound System or Equipment Used*
Imaging Technology (MRI, US, CT, Other (please explain)
Stage of Research*
Mechanism of Action*
Clinical Indication*
Keywords*
Microbubble
Drug Therapeutic
Clinicaltrials.gov URL
What is your hypothesis? (500 characters)*
What research question do you hope to answer? (250 characters)*
What problem are you trying to solve? (500 characters)*
Why is this problem important to solve? What impact will this have on patient care? (1000 characters)*
How is it done today? What are the limitations of existing approaches? (500 characters)*
What is new about your approach or what new data will your project generate? (500 characters)
If you succeed, how will your results change clinical practice? What additional steps will be needed to adopt your approach in the clinic? (500 characters)*
Please provide a brief description of the project/trial design & methods. What are the project goals? (2500 characters)*

Please describe any preliminary data or studies that have been completed to support this application (500 characters).*

Have you secured or are you in the process of securing additional sources of funding for this project?* (500 characters)