**Investigator-Sponsored Research Study Concept Proposal Form**

HistoSonics recommends that investigators interested in conducting an investigator-sponsored research (ISR) study supported by HistoSonics first submit a study concept by completing this form. If HistoSonics determines that the proposed clinical study aligns with current evidence needs and has scientific merit, the investigator will be invited to submit a study protocol and detailed budget.

For the ISR study concept submission, please send the following to [ISRProgram@histosonics.com](mailto:ISRProgram@histosonics.com):

Completed proposal form (see below)

Principal Investigator’s CV

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| --- | --- |
| Sponsor Information | |
| Investigator name: | Click or tap here to enter text. |
| Investigator email: | Click or tap here to enter text. |
| Investigator phone: | Click or tap here to enter text. |
| Institution name: | Click or tap here to enter text. |
| Institution address: | Click or tap here to enter text. |
| Does the institution have a HistoSonics System installed? | No  Yes |
| Study Information | |
| Institutional Review Board (IRB) name: | Click or tap here to enter text. |
| Study title: | Click or tap here to enter text. |
| Name of physician(s) performing histotripsy procedures: | Click or tap here to enter text. |
| Study design: | Prospective  Retrospective  Case study/series |
| Number of sites: | Single center  Multicenter, number of centers: Click or tap here to enter text. |
| Comparison considered in the study (e.g., alternative treatments, performance goal): | No comparison  Single arm with performance goal  Multi-arm  If single arm with performance goal or multi-arm, describe comparison Click or tap here to enter text. |
| Statistics: | Descriptive statistics only  Hypothesis-driven  If hypothesis-driven, describe hypothesis Click or tap here to enter text. |
| Total sample size: | Click or tap here to enter text. |
| Sample size justification: | Click or tap here to enter text. |
| Scientific Rationale/Background:  *Provide a summary of the overall purpose and rationale for this proposed study, including any relevant background information.* | Click or tap here to enter text. |
| Study Objective(s): | Click or tap here to enter text. |
| Study population:  *Provide a brief description of the study population and inclusion/exclusion criteria (e.g., disease, stage)* | Click or tap here to enter text. |
| Describe any planned treatments and/or treatment given prior to histotripsy: | Click or tap here to enter text. |
| Describe histotripsy treatment details:  *Histotripsy dosing (single tumor or multiple tumors, partial or complete tumor treatment, single treatment session or multiple treatment sessions)* | Click or tap here to enter text. |
| Describe any planned treatment and/or treatment given post-histotripsy: | Click or tap here to enter text. |
| Primary endpoint(s): | Click or tap here to enter text. |
| Follow-up schedule:  *Including specific tests/evaluations performed at each follow-up visit (e.g., imaging, tissue, blood, biomarkers, other, QoL)* | Click or tap here to enter text. |
| Expected duration of subject participation (months): | Click or tap here to enter text. |
| Study Timeline | |
| *Provide estimated milestone timing in months (e.g., 3 months for contract negotiation, 2 months for IRB approval, first subject enrolled at 5 months, last enrollment at 20 months, etc.)* | |
| Contracting: | Click or tap here to enter text. |
| IRB approval: | Click or tap here to enter text. |
| First subject enrolled: | Click or tap here to enter text. |
| 50% of subjects enrolled: | Click or tap here to enter text. |
| Last enrollment: | Click or tap here to enter text. |
| Last follow-up visit: | Click or tap here to enter text. |
| Final report submitted to HistoSonics: | Click or tap here to enter text. |
| Presentation at a medical conference: | Click or tap here to enter text. |
| Submission for publication in a peer-reviewed journal: | Click or tap here to enter text. |
| Publication Plan | |
| Presentation / Publication Plans: | Presentation(s) – medical conference(s) & anticipated year: Click or tap here to enter text.  Publication(s) – target journal & anticipated submission date (month/year): Click or tap here to enter text. |
| Requested Support | |
| Amount of financial support requested from HistoSonics: | Click or tap here to enter text. |
| Describe which tests/evaluations will be considered standard of care (i.e., not included in study budget): | Click or tap here to enter text. |
| Will additional support be requested from another company/organization? | No  Yes  If yes, describe support requested and/or received and the status of the support Click or tap here to enter text. |

By signing this form, I agree that:

I am the sponsor and investigator for this proposed study, and

This is my original study idea, and

I have and will retain independent control over the proposed study.

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| --- | --- |
| **Investigator Signature** | **Signature Date** |