**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. | |
| Study Information | | |
| Institutional Review Board (IRB) name: | Click or tap here to enter text. | |
| Main scientific question: | Click or tap here to enter text. | |
| Study design: | Prospective clinical study  Retrospective clinical study | Single center  Multi-center, number of centers: Click or tap here to enter text. |
| Single arm  Multi-arm | Descriptive statistics only  Hypothesis-driven |
| Describe the study population: | Click or tap here to enter text. | |
| Number of patients: | Click or tap here to enter text. | |
| Histotripsy treatment details (describe concomitant therapies, if applicable): | 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, please describe comparison: Click or tap here to enter text.  Multi-arm, please describe comparison: Click or tap here to enter text. | |
| Primary endpoint(s): | Click or tap here to enter text. | |
| Study duration (estimate): | Start-up activities (months): Click or tap here to enter text.  Enrollment (months): Click or tap here to enter text.  Patient follow-up (months): Click or tap here to enter text.  Data analysis / final report completion (months): Click or tap here to enter text. | |
| 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 | | |
| Type of support requested: | HistoSonics Financial Support – Amount requested: Click or tap here to enter text.  Will additional support be requested from another company/organization?  No  Yes  If yes, please describe support requested and/or received for this study: 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** |