

## EXOSOME DIAGNOSTICS SUBMISSION PROCESS

The Exosome Diagnostic Investigator Initiated Research program is open to all physicians, researchers, and institutions in the United States and Europe. In order to ensure adequate review, proposals must be received 60 days prior to the anticipated start of the study. Proposals cannot be submitted past study commencement.

Exosome will accept concise high-level submissions (Stage I - Concept Proposal) to gauge our interest in the proposed research. If the submission is of interest and aligns with Exosome's defined research goals, the PI will be invited to submit a detailed study proposal (Stage II – Protocol Submission) for further review and consideration. Initial interest in a Stage I proposal does not guarantee subsequent approval of the study submission.

The following information is required when submitting a Stage I submission or, if requested, a Stage II submission (various formats accepted - investigator choice). Please submit to [IRR.ExosomeDx@Bio-Techne.com](mailto:IRR.ExosomeDx@Bio-Techne.com).

### (STAGE I (CONCEPT) SUBMISSION

- Investigators contact information
- Investigator curriculum vitae (CV)
- Support type: test or monetary
- Research area of interest
- Study subjects: animal, human, *in vitro*
- Proposal title
- Research hypothesis
- Research objective
- Subject number (#)

### STAGE II SUBMISSION

- Investigators contact information
- Investigator curriculum vitae (CV)
- Copy of medical license
- Organization and payee information
- Funds will be provided only to the organization listed in the application as the payee.
- No funds or product will be provided directly to the Investigator.
- Support type: material transfer agreement) or monetary
- Research area of interest

- Proposal title
- Research hypothesis
- Research objective
- Study design
  - Study subjects: animal, human, *in vitro*
  - Subject number (#)
  - Inclusion and Exclusion Criteria
  - Study drugs/treatment (if applicable)
  - Endpoints (primary/secondary)
  - Statistical plan (if applicable)
  - Estimated project start date
  - Estimated project completion date
  - Abstract/publication timelines (if applicable)
  - Budget

## EXOSOME DIAGNOSTICS REVIEW PROCESS

Exosome will respond via email in receipt of a Stage I submission. All Stage I & II submissions will be reviewed by Exosome medical and scientific personnel. If a Stage I concept proposal is approved by the scientific and medical team, a request for a Stage II submission will be sent to the PI. When a decision on a Stage II submission is finalized, notification will be sent to the PI. Our time for review will depend on submission completion, submission volume, etc. Exosome does not guarantee that it will approve all received requests. Exosome support for any Independent Investigator Initiated Research Grant does not imply any obligation toward and is not in any way connected to the recommendation or prescribing of Exosome Diagnostics' products or services.

## EXOSOME REQUIREMENTS BEFORE INITIATION OF INVESTIGATOR-INITIATED RESEARCH (IIR):

After approval to fund a Stage II submission, Exosome Diagnostics requires the following documents before it can initiate support (test and/or funding).

- Fully executed IIR agreement
- Institutional Review Board (IRB)/Ethics Committee (EC) Approval Documentation (IRB/EC approval letter, IRB/EC approved study protocol and IRB/EC approved informed consent form, (as applicable) or IRB/EC waiver documentation
- Final study protocol
- Registration on [ClinicalTrials.gov](https://clinicaltrials.gov) (if applicable)