**Appendix A: Investigator Initiated Research Application**

Dear Researcher,

Thank you for your interest in bioMérieux’s products. We receive many requests asking for support of studies involving bioMérieux’s instruments and reagents. Generally, they are all very interesting and undoubtedly would benefit the scientific and/or clinical community. Unfortunately, bioMérieux is unable to support them all.

In order to help us more fairly evaluate these proposals, we have created this form in an effort to standardize the data we collect and the evaluation process.

Please complete this form and return it, along with a current CV, to:

**investigations@biomerieux.com**

Please note that bioMérieux makes study support decisions on a monthly basis.

**Project Title**

1. **Principal Investigator**

(include contact information)

1. **Background Information**

(<250 words, include study rationale)

1. **Objectives**

Provide the main study objectives

1.

2.

How the objectives will be assessed, e.g. parameters to be collected and study outcome measures:

1.

2.

1. **Study Design**

(Indicate whether prospective vs retrospective; observational vs interventional; randomized vs not, single center or multicenter)

1. Study population(s) (number, including controls, if applicable):
2. Eligibility criteria:
3. **Study Methods/Procedures**

Describe the main procedures/methods; identify data sources, briefly describe key data to be collected, and duration of study. For retrospective studies, please indicate the time range of the data included and indicate the source of the data.

1. **Analytic Approach/Statistical Analysis Plan**

Provide a brief explanation of how sample size generated, and statistical methods to be used.

* 1. Sample size and justification:
	2. Primary and Secondary Endpoints:
	3. Primary analyses:
1. **Site(s)**

Please describe the site(s) where the research will be performed.

1. Lab organization (i.e. 24 hour lab, 2nd shift lab, etc.)
2. Results reporting (i.e. real time reporting to LIS/MIS, next day reporting of overnight results)
3. If applicable, please describe your institution’s antibiotic stewardship program.
4. **Deliverables and Plan for Dissemination of Findings**

(include conferences, reports and publications planned)

1. **Study Timeline**

(Indicate number of months required for each stage of the project)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Tasks | Month  | Month  | Month  | Month | Month  |
| Protocol development |  |  |  |  |  |
| Site training |  |  |  |  |  |
| Data collection |  |  |  |  |  |
| Statistical analysis |  |  |  |  |  |
| Manuscript preparation |  |  |  |  |  |

1. **Support**

Total project budget:

Existing funding sources and amount:

Amount requested from bioMerieux:

(Equipment costs, etc.)

Reagents/instrumentation request:

What kind:

How much:

Installation and training needed?

Technical support needed?

1. **Additional information**

What benefits do you see for bioMerieux in performance of the study (i.e., why should we be interested)?

Is there anything else you feel we should know about you, your institution, this study, your ability and qualifications to perform this study, or any other pertinent information?

**Appendix B: Proposal Evaluation Form**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **1** | **2** | **3** | **4** | **5** | **Assigned** |
| **Quality of Proposal** | very poorly written | major changes needed | extensive work needed | minor changes needed | very well written |   |
| **Scientific Soundness** | Scientifically unsound  | lacking soundness | sound | very sound | excellent |   |
| **Alignment with bioMerieux business interests** | poorly aligned | some alignment | moderately aligned | well aligned | Very well aligned |   |
| **Experience of the investigative site/lab** | little | some | moderate | very good | extensive |   |
| **Amount of Medical Affairs support required** | extensive | detailed | moderate | some | little |   |
| **Cost** | >$50,000 | $30-50,000 | $20-29,000 | $15-19,000 | $5-14,000 |   |
|  |  |  |  | **Total Score** |   |
|  |  |  |  |  |  |
|  |  |  |  |  |  |