Dear Researcher:

Thank you for your interest in the BioFire® FilmArray® System. The bioMérieux BioFire Investigator-Initiated Study Program (the “Program”) receives many requests asking for support of studies. The Program is open to all academic and community-based physicians and researchers worldwide who are interested in conducting research related to the BioFire System. Proposals must be submitted in English and are reviewed by a committee of medical and scientific staff who meet regularly to review submitted proposals. The attached form was created to standardize the review process. Please take the time to describe the study in adequate detail so that our review committee has a good understanding of the study design, objectives, and workflow.

In reviewing study proposals, we consider whether the proposed study:

* Is well described and has a scientifically valid study design
* Is aligned with bioMérieux BioFire’s research goals of demonstrating the technical, clinical and economic value of the BioFire System to health care providers, administrators, laboratories and payors.
* Provides incremental value to the current body of knowledge regarding the BioFire System
* Complies with regulatory requirements, ethical standards and bioMérieux BioFire’s business standards
* Is conducted by experienced and qualified investigators
* Is expected to result in publication in a peer-reviewed journal or other recognized professional forum within two years of initiation

We support sponsored studies to add to the body of knowledge about the BioFire System. We do not support studies to influence individual purchasing decisions.

For US investigators, BioFire is required by the Open Payments Act to track all transfers of value (including direct payments, the value of loaned instrument and consumables used for research purposes) it provides to covered physicians and teaching hospitals. We are required to report this data to the Centers for Medicare and Medicaid Services in March of each year. The government makes the data submitted available in a public searchable database.

Please complete and return this form to:

**Beth Lingenfelter**

**Senior Director of Outcomes Research**

**BioFire Diagnostics, LLC**

**A bioMérieux Company**

[**beth.lingenfelter@biofiredx.com**](mailto:beth.lingenfelter@biofiredx.com)

**801.736.6354 ext. 415**

**Section1 – Study Information**

**Study Name:**

**Principal Investigator:** (please include a copy of the PI CV with this form)

* Name:
* Title:
* Institution:
* Co-investigator(s)
  + Name:

Institution:

* + Name:

Institution:

* + Name:
  + Institution:

**Study Objectives:**

**What are the specific aims of this study?**

* + **Aim 1**
  + **Aim 2**
  + **Aim 3**

**What is the primary objective of the study?**

**Section 2 - Study Protocol**

Provide a detailed description of the study design and the study work flow. Complete each of the following sections or mark them as N/A. *Note: Providing complete descriptions will streamline the review process.*

1. **Narrative Description of the Study Design (if appropriate, include a description of the intervention group and the control group)**
2. **Provide a narrative description of the study workflow. If necessary, include a table or chart to help describe the study workflow.**
3. **Describe the sample collection process including where samples will be obtained (inpatient, outpatient, ED, retrospective study using archived samples), who typically obtains them and what sample types will be included**.
4. **If applicable, describe how samples are transported to the testing location, including the timeframe between collection and testing. Where will sample be tested (one site, multiple sites)?**
5. **Describe sample processing and testing, including expected time-frames and if additional (non-BioFire) testing will also be performed.**
6. **If applicable, describe the process of reporting test results to clinicians, including the expected timeframes for reporting.**
7. **If applicable, describe current patient management and treatment practices and how BioFire results are expected to impact patient management**.
8. **What are the specific inclusion criteria (patients and/or samples)?**
9. **What are the specific exclusion criteria (patients and/or samples)?**
10. **If the study involves a methodological comparison, provide specific information about the comparison method and how discrepant results will be resolved?**
11. **Describe known limitations to the study design and how they may affect the results. If applicable, describe how they will be addressed.**

**Section 3 - Data Analysis and Statistical plan**

1. **How many samples/patients will be included in the study? Provide a justification for this sample size.** *Note:* *The justification should include a description of the primary objective (e.g., reduced length of stay), the known or expected performance of the control group and the expected change as a result of the intervention (e.g., our current median length of stay for patients with respiratory disease is 3 days, with the faster time to result, we expect the length of stay to be reduced by 0.5 days).*
2. **Which specific variables will be evaluated and how will the data be obtained? If applicable, provide a copy of the case report form or data collection sheet.**
3. **Which statistical methods will be used in the evaluation? Who will perform the statistical analysis?**

**Section 4 – Study Logistics and Publication**

Progress reports are required every three months from study initiation to completion, including presentation or publication of the study results.

1. **What is your anticipated start date?** (*Please allow at least 2 months for protocol review and contracting)*
2. **What is the anticipated duration of the study?**

**IRB/Ethics Board Requirements and Status**

1. **Is IRB/Ethics Board Approval Required? (Please provide a justification if approval is not required)**
2. **Does the study require informed consent?**
3. **What is the current status of the approval?**

*Note: A copy of the IRB/Ethics Committee decision regarding the study must be provided prior to study initiation.*

**Presentation of Results**

**What, if any, sort of publications do you hope for as a result of this study? White paper, poster, abstract, peer reviewed scientific journal?**

*Note: bioMérieux BioFire Medical Affairs teams will require the opportunity to review and provide comments on all publications (abstracts, posters, manuscripts) and all presentations that result from this research project.  With the exception of protecting the proprietary property of BioFire, the author will maintain control over the final content of the publication.*

**Study Registration**

Do you plan to register this study with any organization or on any public databases (e.g., Clinical Trial.gov)? If so, please specify.

**Section 5 – Requested Support**

|  |  |  |
| --- | --- | --- |
| Requested Support | Model/Panel | Quantity/Amount |
| BioFire® FilmArray® Instruments (loaned) |  |  |
| BioFire® FilmArray® Panels |  |  |
| Verification material |  |  |
| Quality Control Material |  |  |
| Financial support |  |  |
| Other Support |  |  |

List any additional requested support.

If financial support if requested, provide a detailed budget.