Multi-Site Study:

Principal Investigator/Contributing Scientist, Test Site Management, and QA Acknowledgement Forms

Your sponsor-selected laboratory has been identified as a participating Test Site in a GLP study to be conducted at Ricerca Biosciences, LLC. As such, the Ricerca Study Director, Testing Facility Management, and Lead QAU would like assurances that the conduct of the phases at the Test Site will be in accordance with GLP · regulations (as specified in the protocol). If the conduct will be other than GLP regulations, please specify.

PLEASE FILL OUT THE ATTACHED FORMS AND RETURN TO THE STUDY DIRECTOR BEFORE STUDY PHASE ACTIVITIES.

Ricerca Biosciences, LLC Study No. _____
Study Director _____
Principal Investigator/Contributing _____
Scientist _____
Contact Information _____
(Name, phone and email address, as appropriate) _____
_____
Test Site Address _____
_____
_____

The completed forms shall be retained in the study file and a copy provided to Ricerca QAU.

Ricerca Management has assigned the role of Lead QAU for this study to:

<QA Auditor Name>
Quality Assurance
Ricerca Biosciences, LLC
7528 Auburn Road
Concord OH 44077
Phone: 440 < >-< >
Fax: 440 < >-< >
e-mail: <auditor email address>

Multi-Site Study:

Test Site Management Acknowledgement Form

Testing Facility Study No. _____
Test Site Project No. _____
Testing Facility Study Director _____
Test Site Principal
Investigator/Contributing Scientist _____
Test Site Management _____

Instructions: This acknowledgement form is to be signed, dated, and returned to the Testing Facility Study Director prior to the initiation of the phase of the study being conducted at the Test Site. Other appropriate means of acknowledging the compliance status of the Test Site are acceptable.

The undersigned declares that:

1. The Test Site participating in this GLP study will conduct their phase of the study in accordance with the following GLP regulations and guidelines (check appropriate boxes, including alternate study conduct regulatory status):

☐ 21 CFR 58 ☐ 40 CFR 160 ☐ 40 CFR 792 ☐ OECD GLPs

☐ Other Federal Regulations _____

☐ Non-GLP if checked, please check one: ☐ GMP ☐ Non-Regulatory

2. Test Site Management and Principal Investigator will have reviewed their section of the protocol prior to phase activity, and ensure that the protocol has been made available to all study personnel.

3. Test Site Management has appointed a Principal Investigator (PI)/Contributing Scientist to be responsible for the phase of study being conducted at that site. Note: This signed document can serve as Test Site Management appointment of the PI.

4. A contributing scientist report on the phase of the study conducted at the Test Site will be submitted to the Ricerca Study Director for inclusion in the final report.

5. At the completion of the study, all data generated during the phase at the Test Site will be archived at the Test Site or Test Site Subcontract Facility. If alternate facilities are selected for archiving, the Study Director shall be notified.

_____ _____
Test Site Management Date

_____ _____
Principal Investigator Date