

## RESEARCH GRANT AGREEMENT FOR INVESTIGATOR INITIATED STUDY

**THIS RESEARCH GRANT AGREEMENT FOR INVESTIGATOR INITIATED STUDY** (the "Agreement") is effective as of the Effective Date indicated below and is between:

- (1) **Radiometer Medical Aps**, a company registered in Denmark, whose principal place of business is at Åkandevej 21, 2700 Brønshøj ("**Radiometer**"); and
  - (2) **Dipartimento Neuroscienze, Biomedicina e Movimento at Università degli Studi di Verona**, an Institution registered in **Italy**, whose principal place of business is at **Via S. Francesco, 22, 37129 Verona VR, Italy**. ("**Institution**"),
- collectively referred to as the "Parties".

### BACKGROUND

RESEARCH DESCRIPTION: [Evaluation of POCT Creatinine](#)

PRINCIPAL INVESTIGATOR: [Professor Giuseppe Lippi](#)

ADDRESS: [Via S. Francesco, 22, 37129 Verona VR, Italy](#)

PHONE: [+39 045 812 4308](#)

Radiometer, on the one hand, and the Principal Investigator and Institution identified above, on the other hand, hereby agree to conduct the "INVESTIGATOR INITIATED STUDY" referred to above in accordance with the following terms and conditions:

### EFFECTIVE DATE IS:

#### 1. INVESTIGATOR INITIATED STUDY OF PRODUCT

- 1.1 The Institution shall conduct its INVESTIGATOR INITIATED STUDY (the "Study") in accordance with the agreed Study Synopsis attached hereto as [Exhibit A](#) and made a part hereof.
- 1.2 The Evaluation will be conducted under the direction of the Principal Investigator with assistance from associates as may be required.
- 1.3 The Institution and Principal Investigator shall use any equipment, property, reagents or materials received from Radiometer only in accordance with the terms hereof, and not for any purpose other than in connection with the Study.
- 1.4 Upon termination or discontinuance of the Study for any reason, all unused reagents or materials and other equipment or property shall be returned to Radiometer at Radiometer's expense.

## 2. GRANT PROVIDED

2.1 In consideration for the performance of the Study:

- a. As part of this Research Grant, Radiometer shall provide to Institution at no charge the following Radiometer products and services (e.g scientific support such as review of protocol and/or publication) ("Radiometer Products") in the quantities listed:

Radiometer Product/Service	Quantity	Representing a value of:
ABL90 FLEX PLUS analyser with Crea (loan to Institution during study period)	1	
ABL90 FLEX PLUS Sensor Cassettes (SC90 Ki). SC has a 2 months shelf life, so the delivery should be done over 2-3 times.	Min. 4 pcs Max. 8 pcs	
ABL90 FLEX PLUS Solution packs (SP90 Ki)	Min. 1 pcs Max. 2 pcs	
Creatinine reagent pack for ROCHE COBAS 8100	1 pcs	

- b. The financial support provided by Radiometer will be of €0.00,- The invoice for the total amount will be sent for payment upon signature of this Agreement and will be payable at 60 days of the invoice date.
- c. Any costs, fees, expenses or otherwise for any study costs above such amount shall be at Institution's sole obligation and expense.

2.2 This Research Grant should not be perceived as an unlawful inducement of to purchase, lease, recommend, use, or arrange for the purchase or lease of its Radiometer products or services.

2.3 Radiometer does not expect any preference for its products.

## 3. RESPONSIBILITY FOR THE INVESTIGATOR INITATED STUDY

3.1 It is the responsibility of the Principal Investigator to obtain any legal or ethical approval that according to local national laws are needed in order to perform the

Study.

- 3.2 It is the responsibility of the Principal Investigator, at reasonable intervals, to inspect the records produced in relation to the Study, in order to verify that the protocol is being adhered to by all personnel involved in the Study, that any deviations to the protocol are being documented. Radiometer can offer support for the monitoring as specified in section 2.1.
- 3.3 It is the responsibility of the Principal Investigator to report any adverse event occurring during the Study period to the appropriate national authorities. This information has to be provided to Radiometer with a period of thirty (30) days.

#### **4. CONDUCT OF INVESTIGATOR INITIATED STUDY**

- 4.1 The Principal Investigator will oversee all elements of the Study, obtain the specified data in accordance with the Study Synopsis, record and analyze all results obtained during the Study. Radiometer can offer support for this part of the Agreement as specified in section 2.1.
- 4.2 In order to verify that the Research Grant is applied solely for the agreed intended research use, if requested by Radiometer, Institution will furnish Radiometer Study Evaluation-related documentation, such as a copy of the research protocol, a copy of the ethics committee and/or regulatory approvals or a copy of the Study report upon completion or earlier termination of the Research.

#### **5. COMPLIANCE WITH LAW**

- 5.1 The Principal Investigator and the Institution and each of their employees and agents will comply with all laws, regulations and ordinances in the performance of this Agreement including but not limited to, those relating to occupational safety and health and those promulgated by the relevant authorities including any required Institutional Review Board review of the Research.
- 5.2 Full disclosure is required of Radiometer and of the Research Grant by the Institution and the lead-investigator in all oral or written presentations of the results.

#### **6. REPORTING**

The Parties agree that both Parties will report to the responsible authorities and/or disclose the mandatory details in accordance with mandatory legal requirements or any applicable industry regulations on the cooperation of the pharmaceutical/equipment industry with medical professionals.

#### **7. CONFIDENTIAL INFORMATION**

- 7.1 Confidential Information shall mean any and all information which is disclosed to Institution by Radiometer after the Effective Date of this Agreement and which is in tangible form or other medium of expression, such as writings, drawings, photographs, samples, magnetic tapes or models (or if disclosed orally, is reduced

to written form within thirty (30) days after such disclosure) and which is designated as confidential by Radiometer.

- 7.2 For a period of five (5) years from the Effective Date, Institution shall exert the same level of effort that it employs to keep Institution's confidential information private to maintain confidentiality of Confidential Information. However, Institution and/or Investigator shall have no obligation of confidentiality to such information that:
- a. is publicly available prior to the date of disclosure by Radiometer or becomes publicly available thereafter through no wrongful act of Institution or Investigator;
  - b. is known to Institution or Investigator prior to the date of disclosure or becomes known to Institution or Investigator thereafter from a third party having an apparent bona fide right to disclose the information;
  - c. is independently discovered or developed by Institution or Investigator; or,
  - d. is required to be disclosed by law.

## **8. PUBLICATIONS AND PRESENTATIONS**

- 8.1 Institution's obligations hereunder with respect to confidentiality and non-use will be modified to permit the publication or other presentation of the results of the Study by Institution in a manner which fairly sets forth the conclusions reached. Nonetheless, Radiometer offers as a service, detailed in section 2.1, :
- a. to review for factual errors and make comments on any such publication,
  - b. to make any results from the Agreement known to its customers.
- 8.2 Institution agrees to delay any publication or presentation up to six (6) months if Radiometer requests a delay for the purpose of filing a patent.
- 8.3 Radiometer shall have the right to purchase reprints from any journal in which any publication resulting from the Study may appear, at the price charged to the Principal Investigator/Institution by the publisher.
- 8.4 Institution allows Radiometer to reference the result of the Investigator Initiated Studies for communication purposes, such as e.g. quotes on websites, marketing material or other promotional activities. No reference will take place without proper credit to the Investigator and/or author of published material.

## **9. OWNERSHIP**

- 9.1 All data, information, results, inventions, discoveries, and conclusions, in each case, whether made by Institution or jointly with others, related to, or constitute any improvements to, any intellectual property of Radiometer or its licensors, including, but not limited to, intellectual property pertaining to Radiometer Products, generated during the course of this Study (the "Radiometer Improvements") shall

be promptly disclosed to Radiometer and, from the moment of its creation, be the sole and exclusive property of Radiometer, subject only to the limited rights of the Institution to publish it in accordance with the limitations and provisions of Section 8 hereof.

- 9.2 Patient information and data obtained from Institution source documents and patient history documents shall remain the property of Institution.
- 9.3 With respect to all other data, information, results, inventions, discoveries, and conclusions, in each case, that are not Radiometer Improvements or other intellectual property of Radiometer, (the "Non-Radiometer Improvements") generated in the course of or related to the Study, whether made by Institution or jointly with others, fixed in any tangible medium of expression and resulting from or suggested by the Study, Institution hereby grants Radiometer a royalty free and other fee-free, perpetual, non-exclusive license to make use of, reproduce, market, sell, distribute, sublicense, adapt, modify and publically distribute, any of the Non-Radiometer Improvements solely owned by the Institution, for commercial purposes, research purposes and educational purposes, in each case, in connection with the design, development, manufacture, marketing, and distribution of products of Radiometer.
- 9.4 The Institution agrees that it shall require the Investigator and all other employees and consultants that will be working on the Study to assign to Institution all inventions, data and know-how created, developed or made by them and related to any improvements to Radiometer Products during the course of their employment with Institution.
- 9.5 Institution agrees to and shall execute any documents and instruments necessary to inure all such rights to Radiometer and to allow Radiometer to file, prosecute, issue and maintain any patents relating to the Radiometer Improvements.

## **10. INDEMNIFICATION**

- 10.1 Radiometer agrees to and shall defend, indemnify and hold Institution and its directors, trustees, employees, and staff harmless from and against any injury to persons or damage to property, to the extent that such injury or damage is caused by or arises out of the negligence or the reckless or intentional misconduct of Radiometer or its employees or agents.
- 10.2 Institution and Principal Investigator agree to and shall defend, indemnify and hold Radiometer and its employees harmless from and against any injury to persons or damage to property, to the extent that such injury or damage is caused by or arises out of the negligence or the reckless or intentional misconduct of Institution and Principal Investigator or its directors, trustees, employees or staff in carrying out the Study.
- 10.3 Any party entitled to indemnification hereunder shall give the indemnifying party prompt notice of any covered claim, shall provide the indemnifying party with the opportunity to defend against the claim, and shall reasonably cooperate in such defense.

## **11. REPRESENTATIONS**

The Principal Investigator and Institution each represent and warrant that they are authorized to conduct the Study and that the terms of this Agreement are in accordance with the rules and regulations of the Institution and any other applicable governing body and are not inconsistent with any other contractual or legal obligation of either the Principal Investigator or Institution.

## **12. TERM AND TERMINATION**

- 12.1 This Agreement shall take effect on the Effective Date and shall continue in force for the length of the Research
- 12.2 Radiometer may terminate this Agreement without cause, by giving thirty (30) days prior written notice thereof to the Principal Investigator and Institution.
- 12.3 Upon such termination, the Principal Investigator and the Institution will promptly return any unused reagents and loaned equipment supplied by Radiometer.

## **13. GOVERNING LAW**

- 13.1 If any dispute arises in relation to this Agreement, the Parties shall first attempt to settle the matter by negotiation.
- 13.2 This Agreement and any dispute or claim arising out of or in connection with it shall be governed by and construed in accordance with the laws of Denmark and the courts having jurisdiction over the place where Radiometer has its registered office shall have exclusive jurisdiction over any disputes related to or arising from this Agreement.

## **14. GENERAL PROVISIONS**

- 14.1 The Principal Investigator and the Institution will be deemed to be and function as independent contractors of Radiometer, and not employees or agents of Radiometer and will have no authority to commit Radiometer to any course of conduct or responsibility.
- 14.2 This Agreement and the Study Synopsis constitutes the entire agreement and understanding between the parties relating to the Study, and supersedes all other prior written and oral agreements and understandings.
- 14.3 This Agreement (including the Synopsis) may not be amended or modified except by means of a written instrument signed by the Parties, which states that it is an amendment or modification to them.
- 14.4 Radiometer may assign to any of its affiliates, this Agreement and the rights and obligations hereunder however the Institution nor the Principal Investigator may not be assign or delegated this Agreement without written permission from Radiometer.

IN WITNESS WHEREOF, the parties have caused this Agreement to be duly executed by their authorized representatives.

**Dipartimento Neuroscienze, Biomedicina e Movimento  
Università degli Studi di Verona  
Via S. Francesco, 22, 37129 Verona VR, Italy**

Signature: \_\_\_\_\_

\_\_\_\_\_ Date

Name: Prof. Andrea Sbarbati

Title Director of Neurosciences, Biomedicine and Movement Sciences

**PRINCIPAL INVESTIGATOR**

Signature: \_\_\_\_\_

\_\_\_\_\_ Date

Name: Prof. Giuseppe Lippi

Title: Director of Clinical Biochemistry

**RADIOMETER**

Signature: \_\_\_\_\_

\_\_\_\_\_ Date

Name:

Title: \_\_\_\_\_