THERAPIES. HAND IN HAND.

BSN medical

an Essity company

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BSN medical GmbH • P.O. Box 570239 • 22772 Hamburg • Germany

Fundación Pública Andaluza para la Investigación
de Málaga en Biomedicina y Salud (FIMABIS)
Natalia Andere
Calle Doctor Miguel Díaz Recio 28
29010 Málaga
Spain

January 21, 2019

Study Contract CUCO-UV

Dear Natalia,

please find attached both copies of the study contract to the study CUCO-UV.

I kindly ask you to start the signature process. Please send us one of the copies back after having collected the manual signatures of Dr, Morales, Dr. Morilla and your Managing Director. The other copy is for your internal documentation.

Please send our copy of the study contract to my attention:

BSN medical GmbH
Christine Wagner, BF 469
Heykenaukamp 10
21147 Hamburg
Germany

Please do not hesitate to contact me in case of any questions.

Thank you very much for your assistance.
Best regards

Christine Wagner

Christine Wagner
Clinical Project Manager
Tel. + 49 40 4909-6155
Fax + 49 40 4909-6730
christine.wagner@essity.com

Agreement on the Funding and Product Supply of a Non-commercial Clinical Investigation

(Investigator-Sponsored Study)

between

BSN MEDICAL GMBH, QUICKBORNSTRASSE 24, 20253 HAMBURG, GERMANY
- hereinafter referred to as the "**Funder**"

and

Fundación Pública Andaluza para la Investigación de Málaga en Biomedicina y Salud (FIMABIS)
- hereinafter referred to as the "**Sponsor**"

and

1. Professor José Miguel Morales Asencio. Head of the Department of Nursing and Podiatry. University of Málaga (Spain). Principal investigator of the Research Group CTS-970.
2. Dr Juan Carlos Morilla Herrera. Director of the Case Management Unit of the District of Primary Health Care of Málaga and Clinical Associated Professor of the Department of Nursing and Podiatry. University of Málaga (Spain).

- hereinafter referred to as the "**Principal Investigators**".

Principal Investigators and Sponsor are hereinafter collectively referred to as "**Researcher**".

Sponsor and Funder are hereinafter each referred to as "**Party**" and collectively as "**Parties**".

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Version 1.0

Preamble

The Funder produces and markets medical products focusing on surgical dressing, orthopedics, phlebology and lymphology. As such, the Funder is interested in the research results as well as the scientific implications for its future product development. The Funder is neither the principal nor the sponsor of the clinical investigation and is in no way responsible for its conduct. The Funder shall by no means control the design, conduct, recording, monitoring and reporting of the clinical investigation.

The Sponsor is an institution intending to conduct a clinical investigation and possesses facilities and personnel with the requisite skills, expertise and knowledge to assume the full and exclusive responsibility of a sponsor conducting a clinical investigation.

The Principal Investigator has specific expertise in the treatment of patients with VENOUS LEG ULCERS and the conduct of clinical investigations.

In this Agreement, the Parties agree on the terms and conditions of the financial funding and Product Supply for the Sponsor's clinical investigation aimed to evaluate the management of colonization and infection of venous leg ulcers. The clinical investigation is meant to obtain and document clinical data on the application of CUTISORB (the "**Product**") and is hereinafter titled: "Effectiveness of a hydrophobic dressing for microorganisms in the control of colonization and infection of vascular ulcers. Controlled, randomized, open study with blinded end-point (PROBE trial). CUCO-UV Study (the "**Study**").

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§ 1 Researcher Obligations

1.1 Sponsor shall conduct the Study as thoroughly described (including rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and record-keeping) in the protocol attached to this Agreement as **Exhibit A**, which, including any amendments, constitutes an integral part of this Agreement (the "**Protocol**"). The Study shall commence on the date specified in the Protocol and is expected to continue over a period from [01-01-2019] to [30-01-2021].

1.2 Sponsor shall apply for and obtain any necessary authorizations, licenses, clearances, approvals or affirmative evaluations, for the Study. Sponsor shall ensure that the Study is conducted in accordance with this Agreement, the provisions of the Protocol, the terms and conditions of the approval for the Study from the governmental, administrative or professional body having authority under applicable laws to regulate in respect of the conduct of clinical investigations and all ancillary matters related thereto ("**Regulatory Authorities**") and all applicable international, national, and local laws, rules and regulations, including Sec. 299a,b German Criminal Code [StGB] (all the above, collectively, "**Applicable Laws**"). In the event of a conflict between the Protocol and this Agreement, this Agreement will prevail. If Funder's assistance or participation is necessary in order to obtain such licenses or comply with such Applicable Laws, Sponsor will promptly notify Funder and aid Funder in providing any such assistance or participation.

1.3 Researcher shall finalize and be responsible for the Protocol, the investigator's brochure, information for investigation participants and obtaining and properly documenting informed consent from each subject participant to the Study or his or her legal representative, ensuring compliance with all Applicable Laws governing data protection and privacy (e.g. Declaration of Helsinki, General Data Protection Regulation).

1.4 Professor José Miguel Morales Asencio and Dr Juan Carlos Morilla Herrera shall be responsible for the conduct of the Study as the Principal Investigators and warrant to be fully qualified by education, training and experience to assume responsibility of the proper conduct of the Study pursuant the Applicable Laws and that they are sufficiently familiar with the Protocol and the Product.

1.5 Principal Investigators shall conduct the Study in accordance with the Applicable Laws.

1.6 Insofar as the aim of the Study is to merely document knowledge of the clinical performance and safety of the Product in daily clinical practice, the Product bears the CE mark, is used within the scope of its designated purpose and no additional invasive or other stressful examinations shall be conducted, the Study may be subject to the less stringent provisions of Sec. 23b of the German Medical Devices Act [MPG].

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1.7 Sponsor represents that [all of the Sponsor's personnel that may perform services hereunder are the Sponsor's employees or affiliates, and warrants that they will abide by the terms and conditions of this Agreement as if each were a party hereto.

1.8 Sponsor shall contract with other involved centers [(Health Centers of Distrito Sanitario Málaga-Valle del Guadalhorce, Área de Gestión Sanitaria Norte de Málaga and Distrito Sanitario Costa del Sol) to support collecting the agreed number of Study subjects. Sponsor shall require by contract, and warrants that, any other centers that become involved in the enrollment of subjects in the Study will abide by the applicable terms and conditions of this Agreement, including, but not limited to Confidential Information, Intellectual Property, the use of the Study Data (all as defined below) and Publications pursuant to Clause 5 as if each were a party hereto.

1.9 Sponsor shall notify Funder immediately (i) of any intended changes or amendments to the Protocol or to any necessary authorizations, licenses, clearances, approvals or affirmative evaluations obtained by the competent Regulatory Authority and provide Funder with a reasonable opportunity to review and comment upon these, (ii) if the status of the Study changes to a commercial clinical investigation, and (iii) if any necessary authorization, license, clearance, approval or affirmative evaluations by a Regulatory Authority is withdrawn by the competent Regulatory Authority. Protocol changes shall be in writing and will not take effect until approved by the competent Regulatory Authority. However, Researcher shall have the full and final discretion over changes to the Protocol and will notify Funder when any changes have been finalized.

1.10 Sponsor shall keep Funder fully informed of the status and the progress of the Study and shall provide Funder with written status reports on a monthly basis according to a template provided by the Funder.

1.11 Sponsor shall provide Funder with (i) copies of all reports and records related to the Study and submitted to a Regulatory Authority, (ii) any authorization, license, clearance, approval or affirmative evaluation obtained from a Regulatory Authority in relation to the Study, and (iii) any correspondence with a Regulatory Authority in relation to the Study.

1.12 Sponsor is responsible for the management and reporting requirements of safety data and adverse event reports from the Study to the competent Regulatory Authority. Sponsor shall report all unexpected or serious adverse events and deaths related to the Study to the appropriate regulatory authorities in accordance with applicable regulations and will provide Funder with copies of those reports within one (1) working day after reporting (working day being a day on which authorities and/or banks are ordinarily open for business in Spain). Sponsor will promptly make available to Funder such records as Funder may deem necessary to investigate and/or report on an adverse event associated with the use of the Product during the Study. Sponsor shall promptly report to Funder any incident in which the Funder's Product malfunctioned and the Product would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

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1.13 Sponsor is responsible for determining whether local law or national law requires that the Study be registered publicly. If local or national law requires registration of the Study, the Sponsor agrees to register the Study and its results in accordance with those laws, rules and regulations and to notify Funder of the registration upon completion. Sponsor understands that failure to register the Study, if required by law, may result in Sponsor's inability to publish the results of the Study.

1.14 Researcher shall not use BSN's name or trademarks without BSN's express prior written consent, except in order to implement clause 1.15.

1.15 In compliance with the obligations on transparency which in its case come legally imposed to Sponsor, this Agreement will be published to ensure transparency of its activity. The limits to the right of access to public information laid down in the basic regulation will apply, and especially, the one arising from the personal data protection.

§ 2 Funding

2.1 Funder agrees to support the financing of the Study up to a total amount of 188.224,48.-€ consisting of a payment of no more than 138.050,52 € on the basis of the Cost Calculation provided by Sponsor attached to this Agreement as Exhibit B and the Product supply for the Study up to a market value of no more than 50.173,96 € (also based on a product cost calculation attached to this Agreement as Exhibit B).

2.2 Such total amount consists of (i) up to:
– 4.455 Cutimed® Sorbact® dressings, market value of 10.878,56 €
– 4451 Aquacel® AG Extra dressings, market value of 39.295,40 €
and (ii) a financial contribution of up to 138.050,52.-€ which will be provided in installments in accordance with the Milestones below. Products will be solely for use in the Study and according to its standard processes.

Milestones	Deliverables	Expected
1. 30% - 41.415,16 €	Signature of contract	21/12/2018
2. 10% - 13.805,05 €	First patient in (FPI)	15-28/02/2019
3. 15% - 20.707,58 €	153 patients (75%) finished the study	15/02/2020
4. 20% - 27.610,10 €	Last patient out (LPO)	15/09/2020
5. 15% - 20.707,58 €	Presentation of abstract of study results in the form of a report	15/11/2020
6. 10% - 13.805,06 €	Submission of publication	15/01/2021
Total: 138.050,52 €		

Sponsor shall not invoice Funder for any fees until the respective services have been successfully completed. The payment shall become due 14 (fourteen) working days after receipt of an invoice by Sponsor, however not before submission of the complete documentation to Funder, as stipulated in this Agreement.

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2.3 Researcher shall use any support provided by Funder solely for the purpose of this Study and spend the funds according to the Protocol and the Cost Calculation attached as **Exhibit A and B** respectively. If the actual number of subjects is lower than the anticipated enrollment or if any funds are not used in the Study, Sponsor will refund to Funder any funds not used.

2.4 Sponsor will send its invoices to:

BSN medical GmbH
BF469 Christine Wagner
Heykenaukamp 10
21147 Hamburg
Email: Christine.Wagner@bsnmedical.com

2.5 BSN will make payment to the following bank account of Sponsor:

[NOTE: PLEASE INSERT:
Bank name: **Caixa Bank S.A.**
Bank address (including city, state and ZIP): **Plaza Cavana, 4. Oficina 2584. 29780 NERJA**
IBAN and Account number: [redacted]
Swift code]: **CAIXE**[redacted]

§ 3 Compliance with Laws

3.1 Researcher will comply with all applicable laws and regulations (whether of Germany or of the jurisdiction in which Sponsor or Study subjects are located) governing confidentiality and the protection of personal data, health or medical information, or Study subjects' right to privacy (e.g. Declaration of Helsinki, General Data Protection Regulation).

3.2 Likewise, Sponsor informs the Funder that, in compliance with provisions in the EU Regulation 2016/679 of the European Parliament and of the Council, of 27 April 2016, the treatment of the personal data arising from this agreement is subject to the current legislation, according to which:

(a) the personal data you provide will be used for its treatment with the purpose of the management deriving from the agreement, the execution of the obligations arising from it and to contact the parties, if necessary, for a proper relationship, being stored for the time needed to comply with the legal obligations stipulated.

(b) the legal basis of the processing of data is the execution as set forth in this agreement.

(c) personal data will not be disclosed to third parties, unless it is specified in a legal obligation.

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(d) the responsible for processing your personal data is the Fundación Pública Andaluza para la Investigación de Málaga en Biomedicina y Salud and/or the Instituto de Investigación Biomédica de Málaga, whose address is Street Doctor Miguel Diaz Recio, 28, local, 29010, Málaga.

(e) the signatories may contact the Data Protection Officer (DPO) at the following e-mail address dpd.csalud@juntadeandalucia.es.

Parties may exercise their rights of access, rectification and erasure of your personal data, or the limitation or oppose its processing as well as to the portability of your data, requesting it in writing, with a copy of your identity card, to the Fundación Pública Andaluza para la Investigación de Málaga en Biomedicina y Salud whose address is Street Doctor Miguel Diaz Recio, 28, local, 29010, Málaga or by email to fimabis@fimabis.org.

3.3 Principal Investigator and Sponsor represent that they have not been debarred or placed under investigation for wrongdoing by any competent regulatory or law-enforcement authority and that they will provide Funder with prompt written notice in the event of any such occurrence during the term of this Agreement.

§ 4 Study Data

4.1 In consideration of Funder's payments to Sponsor according to Section 2, Sponsor shall provide Funder with an investigation report containing the results of the Study and meeting the standards for the structure and content of clinical investigation reports as set out in ISO 14155:2012 within 3 months after completion or termination of the Study as well as further needed data (collectively, the "**Study Data**"). Funder may reasonably request that the Study Data be in a machine-readable format. Sponsor hereby grants Funder an exclusive, worldwide, fully paid-up, royalty-free, assignable right to use the Study Data, and all such data, images, and reports, for any purpose not otherwise prohibited by law. Sponsor acknowledges its obligation under the applicable data protection laws to de-identify all patient information prior to provision of the Study Data to Funder and Funder accepts such de-identified data.

4.2 The Parties agree that neither Sponsor nor Principal Investigator will disclose any Study Data or materials from the Study (together, the "**Study Materials**") to any third party without Funder's prior express written consent. In addition, the Parties agree that neither Sponsor nor Principal Investigator, nor any sub- or co-investigator and/or any agent or representative of Sponsor or Principal Investigator will:

(a) commercially use any Study Materials;
(b) use any Study Materials with any third party; or
(c) perform any analysis comparing Study Materials to any other third party assay or other similar test without Funder's prior express written consent, which Funder may withhold in its sole discretion.

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§ 5 Publications

5.1 If Sponsor intends to publish results of the Study, it will provide Funder with copies of any proposed publication, including, but not limited to, manuscripts and abstracts, as well as a summary of any presentation relating to the Study at least thirty (30) days in advance of any submission to a journal or publication and thirty (30) days in advance of submission for any scientific meeting. Upon Funder's reasonable request, the Sponsor will remove any information, such as but not limited to, any information relating to marketing, finance, technology, customers, strategic planning, research, development, and computer technology ("**Confidential Information**") provided by Funder. Sponsor will submit a manuscript for publication of the results of the Study within six (6) months of completion of the Study. Sponsor will promptly respond to any comments from the relevant journals and move towards a publication without undue delay.

5.2 If Sponsor does not publish the results of the Study within six (6) months of the completion of the Study, Funder will have the right to present and/or publish at symposia, national or regional professional meetings, in professional journals, or through other means of their choosing, the data, methods and results of the Study undertaken under this Agreement. The Institution hereby grants to Funder a non-exclusive, royalty-free, fully paid-up, worldwide copyright license to use, reproduce, display and create derivative works of any publications resulting from the Study for any purpose.

§ 6 Intellectual Property; Confidential Information

6.1 Funder Property. All materials, know-how and Confidential Information provided to Sponsor or Principal Investigator by Funder are and will remain the sole property of Funder. Nothing contained in this Agreement is intended to convey, express or imply any right to ownership or license in any Funder's property to Researcher.

6.2 Researcher Property. All materials and Confidential Information used by Researcher in the Study that are not Funder property as set forth in Section 6.(a) above are and will remain the property of Researcher. Nothing contained in this Agreement is intended to convey any right to ownership or license in any of Researcher's property to Funder.

6.3 Inventions. The Parties do not intend any Intellectual Property (as defined below) to be created under this Agreement. However, in the event that Researcher conceives any inventions and/or Intellectual Property during the Study and relating to the Funder's materials ("**Funder IP**"), such Funder IP will be solely owned by Funder. Researcher will promptly notify Funder of such Funder IP and Researcher will assign, and will cause its employees to assign, to Funder all of its right, title and interest in such Funder IP to Funder. The Sponsor designates Funder as its agent for, and grants to

MORILLA HERRERA J CARLOS -

Funder a limited power of attorney, solely to enable the foregoing assignment from Sponsor to Funder. The term "**Intellectual Property**" means all present and future trade secrets, copyrights, trademarks, patent applications, patents and other intellectual property, whether registered or unregistered, and moral rights recognized by the laws of any country.

6.4 Any Intellectual Property created outside the scope of this Agreement will belong solely to the Party who created the Intellectual Property.

6.5 Confidential Information. Either Party (a "**Discloser**") may disclose to the other Party ("**Recipient**") certain Confidential Information of Discloser. Recipient agrees to maintain such Confidential Information in the strictest confidence, not disclose such Confidential Information in any way without written authorization from Discloser, and not use such Confidential Information for any purpose other than as necessary for the performance of this Agreement. For the avoidance of doubt, Sponsor, Principal Investigator and Funder are subject to the confidentiality obligations under this Section 6.5. Notwithstanding the foregoing, Confidential Information will not include information that: (i) is publicly available; (ii) Recipient can prove in writing was in its possession prior to receipt from Discloser; (iii) is obtained by Recipient from a third party not under confidential obligation to either Party; or (iv) is required to be disclosed by law; provided that, Recipient promptly provides notice to Discloser of any such disclosure request prior to making any disclosure so that Discloser may assert its own claim to confidentiality.

6.6 Researcher agrees that Funder may publicly disclose or disclose to Regulatory Authorities any payment or other transfer of value to a healthcare professional or a healthcare organization as required by the Applicable Laws.

§ 7 No Payments or Billing

7.1 Other than the funding as set forth in Section 2 above, the Parties agree that neither Party will make payment to the other Party for the performance of this Agreement. Each Party will bear its own costs, expenses and overhead in performing its obligations under this Agreement.

7.2 Sponsor shall not seek any reimbursement for the Products provided by Funder under this Agreement or any other service funded under this Agreement from individuals, insurance companies or any other third party.

§ 8 No Inducement

It is the understanding of the Parties that the compensation agreed under this Agreement is appropriate and represents the fair market value for the services provided and that Funder's support provided under this Agreement imposes no obligation, express or implied, for Sponsor or Principal Investigator to purchase,

prescribe, refer, provide favorable status for, or otherwise support Funder's products and services. This Agreement has not been entered into as any type of reward or inducement for the referral or ordering of any Funder products and services. Sponsor will ensure this likewise in relation to the centers contracted according to Section 1.8 above.

§ 9 Indemnification

Funder is not the sponsor and does not provide any indemnification for the conduct of the Study. Sponsor shall indemnify and hold Funder harmless from any liability, loss or damage arising out of this Agreement, except to the extent that the liability, loss or damage results from the gross negligence or willful misconduct of Funder or its agents in manufacturing, labelling or delivery of the Product.

§ 10 Term and Termination

10.1 Term. This Agreement shall become effective after the Principal Investigator confirms his/her engagement in conducting the Study by signing the notification below and shall terminate upon the completion of the Study as described in the Protocol, which is expected to be [December 31st, 2020].

10.2 Termination due to Insufficient Onboarding of Patients: Funder may terminate this Agreement with thirty (30) days notice, if Sponsor and/or Principal Investigator fail to include at least eight (8) patients per month in this study. In such case, Funder shall make a final pro rata payment on the basis of Milestone 2, if Researcher provides Funder with sufficient Study Data for at least one hundred fifty-three (153) patients in accordance with Section 4.

10.3 Termination for other Cause. Funder may terminate this Agreement with immediate effect if changes to the Protocol materially alter the scientific or medical merit of the Study. In such case, Funder shall make a final pro rata payment on the basis of Milestone 2, if Researcher provides Funder with sufficient Study Data for at least one hundred fifty-three (153) patients in accordance with Section 4.

10.4 Survival. Termination of this Agreement is without prejudice to or limitation on any other remedies or any accrued obligations of either Party. In addition, Sections 4, 5, 6, 7, 8, 9, 10.3, and 12 will survive any termination or expiration of this Agreement.

§ 11 Insurance

Sponsor is maintaining and will maintain in full force and effect during the term of this Agreement valid insurance policies that provide the type of insurance and amount of coverage reasonably appropriate for the activities it is expected to perform under this Agreement. Upon request, Sponsor will provide to Funder a certificate of coverage or

other written evidence reasonably satisfactory to Funder of such insurance coverage. Sponsor will notify Funder of any material change, disruption or cancellation of its insurance coverage within thirty (30) days of such change, disruption or cancellation.

§ 12 Miscellaneous

12.1 Assignment. Researcher will not sell, transfer, assign, delegate, pledge or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or obligations under this Agreement without the prior written consent of Funder.

12.2 Severability; Waiver. No waiver by a Party of any breach of this Agreement will be a waiver of any preceding or succeeding breach. No waiver by a Party of any right under this Agreement will be construed as a waiver of any other right. If any provision of this Agreement is found by a court of competent jurisdiction to be unenforceable, that provision will be severed and the remainder of this Agreement will continue in full force and effect.

12.3 Governing Law. The German law governs this Agreement without giving effect to any conflicts of law principles that would require the application of the laws of another jurisdiction. The parties expressly consent to the exclusive venue and jurisdiction of the courts of Hamburg in Germany.

12.4 Notices. All notices or other communications that are required or permitted hereunder will be in writing and delivered personally, sent by email or registered courier as follows:

To Sponsor:

Attention: JOSE MIGUEL MORALES ASENCIO / JUAN CARLOS MORILLA HERRERA / Natalia Andere
Email: jmmasen@uma.es
Cc:] jmorilla20@gmail.com; Natalia.andere@fimabis.org

To Funder:

BSN medical GmbH
Quickbornstraße 24, 20253 Hamburg

Attention: BSN medical GmbH
BF469 Christine Wagner
Heykenaukamp 10
21147 Hamburg

Email: Christine.Wagner@bsnmedical.com
Cc: Julia.Otte@bsnmedical.com

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Or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance with this Agreement.

12.5 Entire Agreement; Modifications. This Agreement, together with its Exhibits, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the conduct of the Study and all prior agreements, understanding, promises and representations, whether written or oral, with respect thereto are superseded by this Agreement. Each Party confirms that it is not relying on any representations or warranties of the other Party except those that are expressly made in this Agreement. No amendment or modification of this Agreement will be binding upon the Parties unless made in a writing referencing this Agreement and duly executed by both Parties. A PDF or any other type of copy of an executed version of this Agreement signed by a party is binding upon the signing party to the same extent as the original of the signed Agreement.

12.6 Relationship of the Parties. The Parties agree each is an independent contractor, and the Parties' relationship will not constitute a partnership, joint venture or agency relationship. Neither Party will have the authority to make any statements, representations or commitments of any kind, or to take any action, which will be binding on the other Party, without the prior written consent of the other Party to do so. All persons employed by a Party will be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment will be for the account and expense of such Party.

The Parties' duly authorized representatives have signed below. This Agreement may be signed in counterparts.

BSN medical GmbH

Place, Date: Hamburg, 07/01/2019

By:

Name: Erik Korte

Title: Managing Director

By:

Name: Dr. Timo Rosenkranz

Title: Authorized Representative

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Fundación Pública Andaluza para la
Investigación de Málaga en Biomedicina y Salud
(FIMABIS)

Place, Date: 20/12/2018

Name: D. José Miguel Guzmán de Damas

Title: Managing Director

The Principal Investigator acknowledges that he is an employee of the Institution, has read this Agreement, and understands his obligations hereunder.

Professor José Miguel Morales Asencio

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PRINCIPAL INVESTIGATOR

Dr Juan Carlos Morilla Herrera

MORILLA HERRERA J CARLOS - [redacted]

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PRINCIPAL INVESTIGATOR

EXHIBIT A
PROTOCOL