



Marlene and Paolo Fresco Institute for Parkinson's and Movement Disorders
Department of Neurology

222 East 41st Street, 13th floor, New York, NY 10017 • Tel 212.263.4838 • Fax 212.263.4837 • <http://nyulangone.org/frescoinstitute>

September 27, 2021

University of Perugia,
p.le Giorgio Menghini 1,
Perugia, 06129

University of Messina Medical Center
Via Consolare Valeria
Messina, 98125, Italy

Re: *Clinical, biochemical and MRI biomarkers of olfactory dysfunction in early Parkinson's disease*

Dear Dr. Simoni and Prof. Quartarone:

On behalf of NYU Grossman School of Medicine (“NYUGSoM”), an administrative unit of New York University, and the Marlene and Paolo Fresco Institute for Parkinson’s and Movement Disorders at NYU Langone Health (“FI-NYU”), we are pleased to award a three (3) year research grant to the University of Perugia (“UNIPG”) as principal site and University of Messina (UNIME”) (collectively, “Awardees”) of up to US \$200,000 in support of the research outlined (“Grant”) in the proposal you submitted for our review on 29 March 2021 (“Proposal”). The Principal Investigator (“PI”) of the Grant is Dr. Simone Simoni and the Co-Principal Investigator (“Co-PI”) is Prof. Quartarone. This Grant is awarded to you under the administrative oversight of the FI-NYU. Payments will be made based on specific milestones, the first of which will be the execution of this Agreement and your submission and the FI-NYU acceptance of a detailed budget, outlining expenses and annual goals for each year of the Grant (“Financial Plan”), as further described in Exhibit A. Grant funds will be released to each institution (“Center”) according to the payment schedule (“Payment”) as further described in Exhibit B, presented with the Financial Plan. Intermediate milestones will be based upon your submission, and the FI-NYU’s acceptance, of a written annual report documenting the use of the prior year’s funds and achievement of the prior year’s goals (“Annual Report”). The number and timing of the Annual Reports is further detailed below. The final payment, will be provided upon your submission and FI-NYU’s acceptance of a written final report documenting the use of funds and achievement of goals covering the full term of the Grant (“Final Report”). These Grant funds shall be used only to support the research plan outlined in the Proposal and no other activities may be supported without mutual written agreement in advance. These Grant funds are to be used to support budgeted activities over term of the Grant, which is up to three (3) years.

The Financial Plan will include line items for each individual compensated with Grant funds, expenses, and fees associated with the project and will address the use of all of the Grant funds. The Financial Plan will also provide details on capital expenditures, such as durable laboratory

equipment, that will be purchased with Grant funds for any durable equipment you intend to purchase for over US \$3,000. A quotation must be submitted and approved from the FI-NYU before the purchase of any durable equipment over US \$3,000. The Financial Plan must disclose any relevant conflicts of interest or appearances of impropriety rising to a level of conflict of interests, including, but not limited to, any family relationships among Grant funded individuals. Grant funds may not be used for any purpose other than the research project described in the Proposal, except by mutual agreement. The Financial Plan should describe how the Awardees oversee institutional finances to prevent fraud and abuse. The Grant funds will only be released on acceptance and annual review of the Financial Plan. All costs associated with this Agreement will be consistent only with the awarded Grant funds and may not be used for any administrative or institutional overhead or indirect costs. We reserve the right to request additional details regarding the Financial Plan at our discretion.

Each Center shall submit an invoice or documentation sufficient for NYUGSoM to determine a payment is due according to the schedule set forth in Exhibit B. Each invoice must be submitted with a signed statement by an independent agent of your Center from the office of sponsored research or another administrative official. This statement will represent an independent attestation as to the completeness and accuracy of the invoice and all submitted reports. Invoices and any other questions or concerns involving invoice receipts or payments should be directed to NYUGSoM and the FI-NYU by e-mail to FI-Neuroscience@nyumc.org and Monica.Norcini@nyulangone.org, or to any such other address as NYUGSoM and the FI-NYU shall provide to the Center from time to time.

If a Center reports a balance of unobligated funds in excess of twenty-five percent (25%) of the total amount awarded for the budget period, the Awardee must provide an explanation as to the budgeted discrepancy and indicate plans for expenditure of those excess funds within the current budget year.

The Final Report must be submitted with a signed statement indicating that the budget is complete and accurate, and that no other funds supported budgeted expenses. This statement will represent an independent attestation to the completeness and accuracy of the financial statements provided in the Final Report. At the completion of the Grant, you will be responsible for providing a complete and independent statement of the use of the Grant funds, reviewed and confirmed to be accurate by an independent agent of your Center from the office of sponsored research or another administrative office. You will serve as the project directors and principal investigators for this program.

Reporting Requirements. As described above, you will submit an Annual Report and a Final Report during the term of this Grant. The Annual Report will provide a detailed narrative of achievements to date, activities underway, and two (2) separate statements of the project expenses, one each from UNIPG and UNIME. The Annual Report is subject to review and acceptance by the FI-NYU prior to the Annual Report being considered complete. The Annual Report will be reviewed according to customary standards for scientific grant reporting. Should you request and the FI-NYU grant an extension to the term of the Grant, an Annual Report will be due at each anniversary of the award date until Final Report is submitted and accepted.

The Final Report will be submitted on or before three (3) years from the date of execution of this Agreement and will consist of a Research Progress Report with two (2) separate independent statements, one each from UNIPG and one from UNIME, of the use of Grant funds, as described above, and at least one (1) published or accepted manuscript describing the completed research and acknowledging the FI-NYU for their support.

All notices related to this Grant should be directed to the FI-NYU by e-mail to Dr. Monica Norcini (Monica.Norcini@nyulangone.org) or to such other address as NYUGSoM and the FI-NYU shall provide to the Center from time to time.

All payments will be made in U.S. Dollars payable by wire transfer as follows to UNIPG:

Bank:	Unicredit Spa
Account Name/Bank	UniCredit Spa filiale di Perugia Elce,
Bank Address:	Viale Orazio Antinori, 99, 06123 Perugia PG
Account Holder Name:	Dipartimento di Medicina e Chirurgia dell'Università degli Studi di Perugia
Bank account number:	000102979271
Swift Code Swift code:	UNCRITMM
IBAN:	IT91N0200803043000102979271

All payments will be made in U.S. Dollars payable by wire transfer as follows to UNIME:

Bank:	UNICREDIT SPA
Account Name/Bank	Unicredit Spa Filiale Via Garibaldi 102 – I 98122 Messina
Account Holder Name:	Salvatore Cuzzocrea
Bank account number:	000300029177
Swift Code:	UNCRITM1K66
IBAN:	IT 16W 02008 16511 000300029177

NYUGSoM and the FI-NYU will be responsible for all wire transfer costs and expenses.

In addition, your acceptance of this funding acknowledges your commitment to:

- Maintain records related to the study for the longer of (i) the period required by applicable law and (ii) three (3) years following the conclusion of this Agreement and not destroying such records without the prior written notice of NYUGSoM and the FI-NYU;

- Notify NYUGSoM and the FI-NYU immediately of any proposed regulatory inspection related to the study or which might affect the Center's performance under this Agreement;
- Adhere to all necessary regulatory requirements at your Center to ensure that your research conforms to all applicable laws and regulations;
- Notify NYUGSoM and the FI-NYU within ten (10) calendar days of the Center's Ethic Committee approval for the project, and;
- Deliver to NYUGSoM and the FI-NYU a copy of any final publications or presentation of data and results.

In any presentation or publication related to the activities supported by this Grant, the Center will acknowledge the support of Mr. Paolo Fresco and Mrs. Marlene Fresco and the support of NYUGSoM and the FI-NYU by including the following statement: "The project described was supported by a grant from New York University School of Medicine and The Marlene and Paolo Fresco Institute for Parkinson's and Movement Disorders, which was made possible with support from Marlene and Paolo Fresco."

You agree that this support comes with the obligation to conduct this research in the public interest and that it is your intention to make public the results of this investigation, in the form of scientific papers and presentations at scientific conferences. You further agree to coordinate public announcements of significant findings from your work with the NYUGSoM and FI-NYU. The parties all agree that the work done under this Grant shall be considered to be the work of you and/or your designee(s). Further, individuals identified by name in the Proposal as members of the research team ("Investigators") may not be changed without mutual consent in writing. If any Investigator is unable to continue to perform their duties under this Agreement, the Awardees and the FI-NYU must agree in writing to a revised Financial Plan. If any Investigator is unable to continue to perform their duties under this Agreement, a change in Investigator must be made by mutual consent within 30 days of the Investigator's last day of availability or this Agreement should be terminated.

Either party may terminate this Agreement by giving not less than thirty (30) days written notice to the other party at any time during the duration of this Agreement and must provide notice of termination if one party is unable to perform its obligations under it. Such notice may be revoked only by mutual consent. Following any termination, NYUGSoM will reimburse the Center for work performed and non-cancelable obligations reasonably incurred prior to the date of termination. To the extent payments made to the Center exceed the work performed and non-cancelable obligations, your Center will be required to return any over-payments made under this Agreement. After any termination, a Final Report must be submitted to NYUGSoM.

Except as needed for NYUGSoM and the FI-NYU to publicize this Grant and for you to acknowledge NYUGSoM and the FI-NYU's support of your research pursuant to this Grant, neither party shall, without the prior written approval of the other party, use the name, symbol or marks of the other party or its affiliates or personnel, in any promotion, advertising, press release or other form of publicity.

You and your Center shall defend, indemnify and hold harmless NYUGSoM and the FI-NYU and each of their officers, trustees, directors, employees, representatives and agents, from and against any and all costs, damages or expenses of every kind and nature (including but not limited to court costs and attorneys' fees and disbursements) arising out of or resulting from your, your research teams, and your Center's performance under this Agreement, including for its negligence, willful misconduct or breach of this Agreement.

EXCEPT FOR CLAIMS COVERED BY THE PRIOR PARAGRAPH, AND NOTWITHSTANDING ELSE ANYTHING TO THE CONTRARY CONTAINED HEREIN, TO THE MAXIMUM EXTENT PERMITTED BY LAW, IN NO EVENT WILL EITHER PARTY BE RESPONSIBLE FOR ANY INCIDENTAL, CONSEQUENTIAL, INDIRECT, SPECIAL, PUNITIVE, OR EXEMPLARY DAMAGES OF ANY KIND, INCLUDING DAMAGES FOR LOST GOODWILL, LOST PROFITS, LOST BUSINESS OR OTHER INDIRECT ECONOMIC DAMAGES, WHETHER SUCH DAMAGES ARISE FROM CLAIMS BASED UPON CONTRACT, NEGLIGENCE, TORT (INCLUDING STRICT LIABILITY) OR OTHER LEGAL THEORY, RESULTING FROM A BREACH OF ANY WARRANTY OR ANY OTHER TERM OF THIS AGREEMENT, AND REGARDLESS OF WHETHER A PARTY WAS ADVISED OR HAD REASON TO KNOW OF THE POSSIBILITY OF SUCH DAMAGES IN ADVANCE.

The Center represents and warrants that it has not been debarred, delisted, disqualified, suspended, or excluded from participating in any health care program. The Center agrees to immediately inform NYUGSoM and the FI-NYU of any such debarment, delisting, disqualification, suspension, or exclusion.

This Agreement constitutes the entire understanding of the parties with respect to the subject matter hereof. This Agreement may be amended or assigned only by mutual agreement as set forth in a writing signed by both parties. You may not assign this Agreement without the prior written consent of NYUGSoM and the FI-NYU. No waiver of any provision of this Agreement shall be binding on any party unless consented to in writing by such party. No waiver of any provision hereof shall constitute a waiver of any other provisions, nor limit or affect such party's rights with respect to any future breach of any of the provisions of this Agreement. If any provision of this Agreement is determined by a court of competent jurisdiction to be invalid, illegal or unenforceable in any respect, such determination shall not impair or affect the validity, legality or enforceability of the remaining provisions hereof, and each provision is hereby declared to be separate, severable and distinct. The Center is an independent contractor of NYUGSoM and the FI-NYU. Nothing in this Agreement shall be deemed to create a partnership or agency or any formal business organization or legal entity among the parties.

Any notice required or permitted hereunder shall be in writing. Notices to NYUGSoM and FI-NYU shall be addressed and sent to NYU Grossman School of Medicine, Attn: Senior Director, Sponsored Programs Administration, 1 Park Avenue, New York, NY 10016 USA, grants.office@med.nyu.edu, and to: The Marlene and Paolo Fresco Institute for Parkinson's and Movement Disorders, NYU Langone Medical Center, 222 East 41st Street, 13th Floor, New York, NY 10017, Attn: Andrew S. Feigin, Executive Director. Notice shall be deemed given as of the

date it is delivered by Federal Express, DHL or an equivalent overnight delivery service, or e-mailed if the receipt of the e-mail is confirmed.

This Agreement shall be governed by and construed in accordance with the laws of the State of New York, in which jurisdiction this Agreement is hereby made, without regard to any applicable conflicts of law. The parties agree that jurisdiction over any dispute arising out of this Agreement shall be in the courts of the State of New York, and hereby expressly consent to and submit to the jurisdiction of said courts.

Please let us know if you need additional information. Please have an authorized signatory for the Center sign and return the executed award to grants.office@nyulangone.org and Monica.Norcini@nyulangone.org. This Agreement may be signed in one or more counterparts, which shall have the same force and effect as an original.

Sincerely,

Anthony Carna
Senior Director, Sponsored Programs Administration
NYU Grossman School of Medicine

Andrew Feigin, MD Executive Director, The Marlene and Paolo Fresco Institute for Parkinson's and Movement Disorders
NYU Grossman School of Medicine

Accepted and Agreed to by:

[UNIPG]

Simone Simoni, MD, PhD, Principal Investigator
Section of Neurology, Department of Medicine and Surgery, University of Perugia

Date: _____

Prof. Lucilla Parnetti, MD, PhD

Date: _____

Director of the Section of Neurology, Department of Medicine and Surgery, University of Perugia

[UNIME]

Angelo Quartarone,
MD, Co-Principal Investigator

Date: _____

Salvatore Cuzzocrea,
Rector, University of Messina

Date: _____

EXHIBIT A

PROJECT PROPOSAL AND FINANCIAL PLAN

EXHIBIT B
PAYMENT SCHEDULE