# **GENERAL RESEARCH GRANT AGREEMENT** (ex-US Grant Recipient; ex-US Study; Single-site)

This General Research Grant Agreement ("Agreement") by and between

Pfizer Inc. a Delaware corporation with an office of business at 235 East 42<sup>nd</sup> Street, New York, NY 10017 ("**Pfizer**") and

University of Messina with an address of via Consolare Valeria 1- AOU Policlinico "G. Martino", Messina, ME, Italy 98128 ("**Grant Recipient**")

is effective as of the date last signed ("Effective Date").

Malgorzata Wasniewska, an employee or contractor of Grant Recipient ("**Principal Investigator**"), has designed and intends to conduct a research study entitled "*ADHERENCE TO GROWTH HORMONE THERAPY AND THE QUALITY OF LIFE IN PEDIATRIC PATIENTS: NEW STRATEGIES OF EVALUATION AND INTERVENTION*," Pfizer Tracking Number 68392533 (the "**Study**"). Pfizer wishes to provide certain funding for the Study. Accordingly, the parties agree as follows:

## 1. STUDY CONDUCT

- 1.1. <u>Protocol</u>. The Study will be conducted by Principal Investigator in accordance with a protocol developed by Principal Investigator (the "**Protocol**"). If Principal Investigator modifies the Protocol in a material way (e.g., changes to timelines, enrollment, dosing), Grant Recipient will promptly inform Pfizer in writing.
- 1.2. <u>Sponsorship</u>. Grant Recipient will not, and will ensure that its employees, staff, agents, consultants, subcontractors and Principal Investigator (collectively, "**Staff**") will not, represent to any third party, including Study subjects, that Pfizer is the regulatory sponsor of the Study. Grant Recipient may delegate duties and responsibilities to its Staff as permitted by Applicable Requirements.
- 1.3. <u>Regulatory Obligations</u>. Grant Recipient is solely responsible for any safety reporting and regulatory obligations associated with the Study.
- 1.4. Compliance with Applicable Requirements. Grant Recipient will conduct the Study and undertake Study-related activities in accordance with Applicable Requirements and ensure compliance with Applicable Requirements by its Staff involved in the Study. "Applicable Requirements" means: (i) the terms of this Agreement; (ii) the Protocol; (iii) the terms of any institutional review board ("IRB") or independent ethics committee ("IEC") and regulatory authority approvals, if required for this type of Study; (iv) all applicable laws, rules, regulations, guidelines or requirements of any federal, national, state or local court, agency, authority, department, regulatory body or other governmental instrument that may be in effect during the performance of the Study in any region or regulatory jurisdiction in which the Study is conducted ("Applicable Law"); (v) all applicable good practice quality guidelines and

regulations encompassing internationally recognized standards such as Good Clinical Practice, Good Laboratory Practice, and Good Review Practice; and (vi) applicable guidelines of the International Council on Harmonisation.

- 1.5. <u>IRB/IEC Approval</u>. If required, Grant Recipient will ensure that the Study is approved by and subject to continuing oversight by an IRB/IEC. If IRB/IEC approval is required, Grant Recipient will provide Pfizer with documentation of the initial IRB/IEC approval and any renewals, and any IRB/IEC-approved amendments to the Protocol. Grant Recipient will notify Pfizer promptly of any withdrawal or suspension of IRB/IEC approval.
- 1.6. <u>Informed Consent</u>. If required, Grant Recipient will obtain written informed consent from each Study subject in accordance with Applicable Requirements or a waiver of consent from the IRB or IEC. Pfizer has no obligation to participate in the development of, or to review or comment on, any informed consent document or request for waiver.
- 1.7. <u>Duration</u>. "**Study Completion**" means the completion of all Study activities, including, if applicable, safety follow-up of all Study subjects and completion of all Protocol requirements. Principal Investigator expects to achieve Study Completion by 01/09/2025.
- 1.8. <u>Status Updates</u>. Grant Recipient will provide Pfizer with an online update of Study progress at least twice a year. Each update will include publication plans, adjustments in the estimated Study Completion date, and any other information reasonably requested by Pfizer.
- 1.9. <u>Study Registration</u>. If applicable, Pfizer encourages Grant Recipient to register the Study and post a synopsis of Study Results, on <u>www.ClinicalTrials.gov</u> or such other website as required by Applicable Law.

## 2. **FUNDING**

- 2.1. <u>Funding</u>. Pfizer will provide funding in support of the Study up to a maximum amount of EUR 61, 500.00, in accordance with the schedule set forth in Attachment A ("**Funding**").
- 2.2. <u>Basis of Support</u>. The Funding is not conditioned on: (i) any pre-existing or future business relationship between Pfizer and either Principal Investigator or Grant Recipient, or (ii) any business or other decisions Principal Investigator or Grant Recipient has made, or may make, relating to Pfizer or Pfizer products. Nothing in this Agreement will be construed in any manner as an obligation or inducement for Grant Recipient or Principal Investigator to purchase, order, prescribe or recommend any product of Pfizer or any Pfizer affiliate.
- 2.3. <u>Submission of Required Documents</u>. Pfizer will not provide any Funding until Pfizer has received documentation of IRB/IEC approval, exemption or waiver (if required), and the Protocol.
- 2.4. <u>Use of Funding</u>. Grant Recipient will use the Funding solely for purposes of the Study. The Funding may not be used to pay physicians or other health care providers or health care institutions for referring potential subjects (if any) for enrollment in the Study. If a third party is

providing funding for the Study, Grant Recipient will use the Funding only for Study activities that are not covered by such third party funding. No portion of the Funding may be used to purchase capital equipment such as computers, iPhones, tablets, appliances, machinery, camera equipment, sensors, etc.

- 2.5. <u>No Charge to Third Parties</u>. Grant Recipient will ensure that no Study subject (if any), insurer, governmental entity or third party payor is charged for any Study-related activities carried out by Grant Recipient using the Funding.
- 2.6. <u>Budget</u>. Grant Recipient represents that the Grant Recipient-provided Study budget upon which the Funding is based reflects an informed, reasonable, estimate of funds required to complete and report the Study, including, if applicable, expenses relating to the publication of Study Results.
- 2.7. <u>Disclosure by Pfizer</u>. In the interest of transparency relating to its financial relationships with investigators and study sites or to ensure compliance with Applicable Law, industry codes and Pfizer policies, Pfizer may report or otherwise publicly disclose payments or other transfers of value to certain health care providers, teaching hospitals and other health care organizations, including the Funding. These laws, policies and codes, and their implementing regulations are collectively "**Transparency Obligations**." Pfizer may disclose in any lawful manner any information necessary for Pfizer to meet its Transparency Obligations.
  - 2.7.1. *Disclosure Content*. Pfizer may identify Grant Recipient and Principal Investigator, and will differentiate clearly between payments or other transfers of value made to institutions and those made to individuals. Disclosures may include identifying information such as name, business address, specialty, and license numbers.
  - 2.7.2. Agreement and Cooperation. Grant Recipient accepts and agrees to these disclosures on behalf of itself and its Principal Investigator. Grant Recipient will reasonably cooperate with Pfizer in Pfizer's collection and disclosure of information necessary to fulfill its Transparency Obligations.
- 3. CONFIDENTIALITY. Any information or materials provided to Pfizer by Grant Recipient related to the Study or the Funding are non-confidential and will not contain any markings claiming confidentiality. Grant Recipient acknowledges that Pfizer will not treat such materials as confidential or assume any obligation to keep them confidential. Grant Recipient's rights with respect to such information or materials will be only those obtained under patent laws and/or under a separate written agreement between Grant Recipient and Pfizer. Grant Recipient has not, and will not, submit any confidential information to Pfizer in connection with the Study or the Funding. Grant Recipient acknowledges that Pfizer may conduct ongoing or future research substantially similar or identical to the Study. Until after release of a Publication by Grant Recipient, Pfizer will not use the Study Report or Protocol for any purpose other than internal review.

## 4. STUDY DATA, RESULTS AND REPORT; PUBLICATIONS

#### 4.1. Definitions.

- 4.1.1. "Study Data" means, as applicable: (i) non-aggregated, subject-level data collected from or about each Study subject; or (ii) the raw epidemiological data collected during the course of the Study, as required by the Protocol.
- 4.1.2. "Study Results" refers to aggregated or summarized Study Data and conclusions about the Study, as would be included in a study report or publication.
- 4.1.3. "Study Report" means a written report of the Study Results.
- 4.2. Use of Study Data and Study Results. Grant Recipient is free to publish the Study Results, subject to the provisions of this Agreement, and owns and is free to use the Study Results for any other lawful purpose. Grant Recipient owns and is free to use the Study Data for its own research, educational, and patient care purposes. In consideration of the Funding, Grant Recipient will not use, or permit others to use, the Study Data for the commercial benefit of any third party.
- 4.3. Study Report. Within six months of the earlier of Study Completion or termination of this Agreement, Grant Recipient will provide Pfizer with a Study Report which may take the form of a manuscript. If the Agreement is terminated early, the Study Report should include, at minimum, the Study Results through the date of termination.
- Publications. Pfizer encourages Grant Recipient to publish the Study Results. Grant Recipient will comply with standard academic practices regarding authorship of scientific publications and recognition of the contribution of other parties in any Publication, including the authorship guidelines promulgated by the International Committee of Medical Journal Editors in effect at the time and disclose Pfizer support of the Study in any Publication. "Publication" means any journal article, abstract, presentation or other type of public disclosure that reports any Study Results.

#### GLOBAL TRADE CONTROL LAWS 5.

#### 5.1. Definitions.

- "Global Trade Control Laws" means the US Export Administration Regulations; US International Traffic in Arms Regulations; economic sanctions rules and regulations implemented under statutory authority and/or the President's Executive Orders and administered by the US Treasury Department Office of Foreign Assets Control ("OFAC"); EU Council Regulations on export controls and sanctions, including regulation nos. 428/2009 and 267/2012; other EU Council sanctions regulations, as implemented in EU Member States; United Nations sanctions policies; other relevant economic sanctions, export and import control laws, and other laws, regulations, legislation, orders, and requirements imposed by a relevant Governmental Entity.
- 5.1.2. "Governmental Entity" means any court, tribunal, or arbitral body with

competent jurisdiction; any military, quasi-military, or law enforcement agency; or any other entity agency, department, authority, or other instrumentality of any supra-national, federal, national, state, county, local, municipal, other political subdivision, administrative authority, agency, commission, instrumentality, or other governmental, regulatory body.

- 5.1.3. "**Restricted Market**" means Crimean Peninsula, Cuba, Donbass Region, Iran, North Korea, and Syria.
- \*\*Restricted Party Lists:\*\* the list of sanctioned entities maintained by the United Nations; the Specially Designated Nationals List and Sectoral Sanctions Identifications List administered by OFAC; the US Denied Persons List, US Entity List, and US Unverified List all administered by the US Department of Commerce; the Consolidated List of Persons, Groups and Entities Subject to EU Financial Sanctions implemented by the EU Common Foreign and Security Policy; the List of Excluded Individuals/Entities published by the US Department of Health and Human Services, Office of Inspector General; any lists of prohibited or debarred parties established under the US Federal Food, Drug, and Cosmetic Act; the list of persons and entities suspended or debarred from contracting with the US Government; and similar lists of restricted parties maintained by the Governmental Entities of the countries that have jurisdiction over activities under this Agreement.
- 5.2. Global Trade Control Laws. The parties and their affiliates and Staff involved in activities under this Agreement, will perform the activities under this Agreement in full compliance with all applicable Global Trade Control Laws.
- 5.3. Restricted Parties; Restricted Markets. Grant Recipient acknowledges that activities under this Agreement will not (i) be in a Restricted Market; (ii) involve individuals ordinarily resident in a Restricted Market; or (iii) include companies, organizations, or Governmental Entities from or located in a Restricted Market. Grant Recipient represents that it is not a Restricted Party and is not owned or controlled by a Restricted Party. With respect to activities performed under this Agreement, Grant Recipient confirms that neither Grant Recipient nor affiliates or Staff directly or indirectly involved in the activities contemplated under this Agreement are Restricted Parties and that no Restricted Parties will be engaged in any activities contemplated under this Agreement or delegated any responsibilities contemplated under this Agreement. Grant Recipient will screen the parties listed above against the relevant Restricted Party Lists. If any part of this representation changes, Grant Recipient will promptly inform Pfizer and suspend all related activities under this Agreement until Pfizer agrees in writing to move forward.

#### 6. TERM AND TERMINATION

- 6.1. <u>Term.</u> This Agreement will commence on the Effective Date and will continue until the later of one year or until terminated in accordance with its terms.
- 6.2. Termination.

- 6.2.1. *Termination Upon Study Completion*. This Agreement will terminate upon Study Completion and each party's receipt of all deliverables and payments owed.
- 6.2.2. *Termination by Grant Recipient*. Grant Recipient may terminate this Agreement: (i) immediately on written notice to Pfizer when, as confirmed by the IRB/IEC, continued performance of the Study poses risks to the health or well-being of Study subjects; or (ii) without cause upon 30 days prior written notice to Pfizer.
- 6.2.3. Termination by Pfizer. Pfizer may terminate this Agreement (A) upon 30 days prior written notice to Grant Recipient if: (i) the Protocol is materially modified in a way unacceptable to Pfizer, (ii) Study conduct is not completed within six months after the expected Study Completion Date, (iii) the Study does not start within six months of the Effective Date, or (iv) if applicable, the Subject enrollment rate is significantly slower than outlined in the Protocol or needed to complete the Study by the Study Completion Date; or (B) immediately upon written notice to Grant Recipient if Principal Investigator becomes unavailable or withdraws from the Study and Pfizer and Grant Recipient are unable to agree upon a successor within 30 days after Pfizer is notified.
- 6.2.4. *Termination for Cause*. This Agreement may be terminated by either party upon written notice that specifically identifies a breach and gives the alleged breaching party 30 days to cure it. Notwithstanding the foregoing, Pfizer may terminate this Agreement immediately upon notice to Grant Recipient, with no cure period, if Grant Recipient violates Global Trade Control Laws or breaches Section 7.3.
- 6.3. Payment upon Early Termination. The terms of this Section apply only if the Agreement is terminated early for a reason other than for cause by Pfizer. If the Funding was not paid in a lump-sum, then upon early termination, Pfizer will pay a pro rata portion of the total Funding, less payments already made. Grant Recipient will refund to Pfizer any Funding already received in excess of this amount except to the extent that such funds have already been used, or are committed and cannot be canceled, in a manner consistent with the Study budget. If the Funding was paid in a lump-sum, then upon early termination, Grant Recipient will refund to Pfizer any Funding received in excess of funds that have already been used, or that are committed and cannot be canceled.
- 6.4. <u>Reconciliation</u>. At Study Completion or termination of this Agreement, Grant Recipient will provide a detailed accounting of the costs and expenses for the Study compared to the budget and Pfizer payments. Grant Recipient agrees to refund any unused, undisbursed or misallocated funds. Upon request from Pfizer based on a good-faith belief that all or some portion of the Funding was not used in accordance with the terms of this Agreement, Grant Recipient will provide Pfizer access to all records related to the Funding to allow Pfizer to verify that the Funding was used in accordance with the terms of this Agreement.

#### 7. REPRESENTATIONS

7.1. <u>Representations of Both Parties</u>. Each party represents that it: (i) has the requisite power and authority to enter into this Agreement and that this Agreement constitutes a legal and valid

obligation binding upon such party, enforceable in accordance with its terms; and (ii) is not a party to any agreement that would prevent it from fulfilling its obligations under this Agreement.

- 7.2. <u>Representations of Grant Recipient</u>. Grant Recipient represents that it, its affiliates and Staff involved in the Study:
  - 7.2.1. are licensed, registered or otherwise qualified and suitable (without restrictions) under Applicable Law to act as a regulatory sponsor, Study site or investigator, as applicable;
  - 7.2.2. are not debarred under subsections 306(a) or (b) of the U.S. Federal Food, Drug, and Cosmetic Act or any other similar Applicable Law and will not use the services of any person debarred under Applicable Law in the Study;
  - 7.2.3. are not the subject of any material past (within the past three years) or pending governmental or regulatory investigation, warning or enforcement action related to its conduct of clinical research that has not been disclosed to Pfizer;
  - 7.2.4. as applicable, are not excluded from, or prohibited from participating in, any national or federal health care program;
  - 7.2.5. have the authority to share business contact information; and
  - 7.2.6. will maintain true, accurate and complete reports, statements, books and other records related to the Study.
- 7.3. Anti-Bribery/Anti-Corruption Representations. Grant Recipient represents that:
  - 7.3.1. the Funding will not cause Grant Recipient, or any individual affiliated with Grant Recipient, to do anything that would result in Pfizer improperly obtaining or retaining business or gaining any improper business advantage;
  - 7.3.2. it will not use any portion of the Funding to directly or indirectly offer or pay any money or anything of value in an effort to influence any Government Official or any other person in order for Pfizer to improperly obtain or retain business or to gain an improper business advantage, and, it has not accepted, and will not accept in the future, such a payment; and
  - 7.3.3. Pfizer will be entitled to revoke the Funding if Pfizer learns that Grant Recipient or any individuals affiliated with Grant Recipient has used or intends to use any portion of the Funding to improperly seek to influence any Government Official or any other person in order to obtain or retain business or gain a business advantage.
  - 7.3.4. For the purpose of this Agreement, "Government" includes all levels and subdivisions of governments (i.e., local, regional, and national; administrative, legislative, and executive) and "Government Official" includes (1) any elected or

appointed non-US Government official (e.g., a legislator or a member of a non-US Government ministry), (2) any employee or individual acting for or on behalf of a non-US Government Official, non-US Government agency, or enterprise performing a function of, or owned or controlled by, a non-US Government (e.g., a healthcare professional employed by a non-US Government hospital or university), (3) any non-US political party officer, candidate for non-US public office, or employee or individual acting for or on behalf of a non-US political party or candidate for public office, (4) any employee or individual acting for or on behalf of a public international organization, and (5) any member of a royal family or member of a non-US military.

7.4. <u>Amendment</u>. Grant Recipient will notify Pfizer promptly if any of these representations require amendment during the term of this Agreement.

## 8. **GENERAL PROVISIONS**

- 8.1. <u>Liability</u>. Each party will be responsible, to the extent permitted by law, for any negligent acts or omissions by itself, its Staff, officers or directors. The Study is not designed, sponsored, or managed by Pfizer and Pfizer provides no indemnification of any type.
- 8.2. <u>Assignment and Delegation</u>. Grant Recipient may not assign any rights or delegate any duties under this Agreement without written permission from Pfizer. If Pfizer authorizes any delegation of duties, Grant Recipient remains responsible to Pfizer for the performance of those duties. Since Pfizer's only obligation hereunder is to provide Funding, Pfizer may assign and delegate its rights or obligations under this Agreement to a third party.
- 8.3. <u>Entire Agreement</u>. This Agreement, its Attachments and the Protocol represent the entire understanding, and supersede all previous agreements, between the parties relating to the Study. This Agreement may be amended only by a written instrument signed by both parties.
- 8.4. <u>Survival</u>. Sections 3, 4, 6.3, 6.4 and 8 will survive Agreement termination, along with any other provision of this Agreement that, by its nature and intent, remains valid after termination.
- 8.5. <u>Use of Names</u>. Neither party will use the name or logos of the other or any of its Staff for promotional or advertising purposes without prior written consent. Grant Recipient is free to identify Pfizer as providing support for the Study in Publications or in publicly available reports of ongoing research studies. Pfizer is free to identify Grant Recipient and the Study in non-promotional listings or reports of Pfizer-supported projects.

[signature page follows]

# IN WITNESS WHEREOF, this Agreement has been duly executed by the parties.

PFIZER INC.	GRANI RECIPIENI	
Authorized Representative	Authorized Representative	
Printed Name	Printed Name	
Title	Title	
Date	Date	
Read and Acknowledged by:		
Principal Investigator		
Printed Name	_	

# **ATTACHMENT A**

# PAYMENT SCHEDULE GRG Tracking # 68392533 TOTAL FUNDING AMOUNT: €61,500.00

Funding includes any overhead allowance.

Milestone(s)	Description	Amount
Initial Payment	To be paid upon receipt by Pfizer of an executed copy of the Agreement, the Protocol and, if applicable, documentation of IRB/IEC approval, exemption or waiver	€61,500.00

<u>Payments</u>: CyberGrants, Pfizer's online grant system, will automatically trigger payment upon completion of a milestone within the system by the Principal Investigator and acceptance thereof by the Pfizer Grant Administrator.

<u>Inquiries</u>: To inquire about a payment, e-mail <u>GlobalMedicalGrants@pfizer.com</u> and include Pfizer Tracking No. **68392533.**