UNIVERSITÁ DEGLI STUDI DI MESSINA

DIPARTIMENTO DI PATOLOGIA UMANA DELL'ADULTO
E DELL'ETA' EVOLUTIVA "GAETANO BARRESI"
(Direttore: Prof. Francesco Stagno d'Alcontres)

IGLC Dissemination & Implementation Research Agreement

This Independent Grants for Learning & Change ("IGLC") Dissemination & Implementation ("D&I") Research Agreement ("Agreement") when signed by all parties is effective as of the date the Agreement is last signed ("Effective Date").

Pfizer Inc, a Delaware Corporation with an office of business at 235 East 42nd Street, New York, NY 10017 ("Pfizer") and

The Department of Human Pathology of Adulthood and Childhood "G. Barresi" of the University of Messina, 1st Consolare Valeria Street, 98125 Messina Italy ("Institution")

Institution investigator OanaRuxandra Cotta ("Principal Investigator") has designed and intends to conduct dissemination& implementation research study entitled "The Sicilian Spoke to Hub Interactive Network for the diagnosis and management of Adulthood Growth Hormone Deficiency"("Study").Pfizer wishes to provide certain support for the Study through Pfizer grant ID 34584263. Accordingly, the parties agree as follows:

1. Investigators and Research Staff

1.1 Principal Investigator. The Study will be conducted by Principal Investigator. Principal Investigator may delegate duties and responsibilities to sub-investigators or research staff only to the extent permitted by applicable laws governing the conduct of clinical investigations.

1.2 Obligations. Institution is responsible to Pfizer for compliance by all personnel who participate in the conduct of the Study, including the Principal Investigator and any contractors or consultants, with the terms of this Agreement.

2. Protocol

2.1 Protocol. The Study will be conducted in accordance with a protocol developed by Principal Investigator ("Protocol"). Approval of the final Protocol by Pfizer is a condition of Pfizer support under this Agreement.

2.2 Amendments. If Principal Investigator modifies the final Protocol approved by Pfizer, Principal Investigator will promptly inform Pfizer IGLC in writing. Continued support by Pfizer will be contingent on Pfizer's review and acceptance of the Protocol changes.

3. Study Conduct

3.1 Sponsorship. Institution is the sponsor of the Study, and not Pfizer. Institution will not represent to any third party, including Study subjects, that Pfizer is a Study sponsor. Regulatory. Institution is solely responsible for all safety reporting and regulatory obligations associated with the conduct of the Study, including, but not limited to, (i) obtaining and maintaining regulatory authorization for the conduct of the Study, if required; and (ii) reporting any Adverse Event or Adverse Drug Reaction to any reviewing IRB, IEC, and regulatory authority as required by applicable laws and regulations.

a. Standards. Principal Investigator will conduct the Study in accordance with the Protocol, International Conference on Harmonization Good Clinical Practice ("ICH GCP") guidelines, to the extent relevant to this type of study, and all applicable law. Principal Investigator will also follow generally accepted research practices for non-interventional studies, such as the Good Pharmacoepidemiology Practices ("GPP") issued by the International Society for Pharmacoepidemiology, the guidances issued by the International Society for Pharmaceconomics and Outcomes Research ("ISPOR"), or the equivalent. Study Registration and Disclosure of Study Results. Pfizer encourages Institution to register the Study on the U.S. National Institutes of Health clinical trials database www.ClinicalTrials.gov or, for relevant non-interventional studies, the European Union Post-Authorisation Study register www.encepp.eu/encepp_studies/indexRegister.shtml before enrollment of the first subject or the start of data collection. Pfizer further encourages Institution to publicly disclose the results of the Study through publication (see Section 7, Publications), posting on a publicly available information repository, or other means.

3.2 IRB/IEC Approval. If required, Principal Investigator will ensure that the Study is approved by and subject to continuing oversight by an appropriate Institutional Review Board ("IRB") or Independent Ethics Committee ("IEC"). As a condition of Pfizer support, Institution must provide Pfizer with documentation of both the initial IRB/IEC approval (or documentation of an exemption)of the final Protocol and annual renewals of that approval if such renewals are required(see Attachment B, Study Documentation Requirements). Institution will notify Pfizer promptly of any withdrawal or suspension of IRB/IEC approval during the term of this Agreement.

3.3 Informed Consent. Principal Investigator will obtain informed consent for each Study subject in accordance with applicable law and will inform Study subjects that Pfizer is providing support for the Study. Pfizer has no obligation to participate in the development of, or to review or comment on, the informed consent form. No Monitoring or Data Collection. Pfizer will not monitor the Study or receive any Study Data (as defined in Section 5, Study Data and Study Results).

3.4 Duration of Study Conduct. Principal Investigator expects to complete Study conduct (enrollment of all Study subjects and completion of all Protocol requirements for each subject) by October 31, 2018 "Study Conduct Completion Date".

3.5 Status Updates. Principal Investigator will provide Pfizer IGLC with an update of Study status, in the form requested by Pfizer IGLC (impactreport), at least once a year during the term of this Agreement, or more frequently if so indicated in Attachment A (Payment Schedule) or if mutually agreed by the parties. Each impact report will include subject enrollment, publication plans, any adjustments in Study Conduct Completion Date, and any other information reasonably requested by Pfizer. Pfizer shall not disclose the Study Results until they are published.

4. IGLC D&I Research Support. Pfizer will provide funding in support of the Study in accordance with the schedule in Attachment A, Payment Schedule. This funding constitutes the "D&I Research Support" for this Study.

4.1 Basis of Support. This D&I Research Support is not conditioned on any pre-existing or future business relationship between Pfizer and either the Principal Investigator or the Institution. It is also not conditioned on any business or other decisions the Principal Investigator or Institution has made, or may make, relating to Pfizer or Pfizer products.

4.2 Submission of Required Documents. Pfizer will not provide any component of the D&I Research Support until Pfizer has received the required documents identified in Attachment B, Study Documentation Requirements.

4.3 Use of D&I Research Support. The Principal Investigator and Institution will use D&I Research Support solely for purposes of the Study. At the completion of the Study, Principal Investigator will confirm in writing that the D&I Research Support has been used only to support the Study by completing a *Certification of Study Closure* form provided by Pfizer. D&I Research funds may not be used to pay physicians for referring potential subjects for enrollment in the Study.

4.4 No Charge to Study Subjects. Institution will not charge Study subjects, insurers, or any other third parties for any Study services covered by D&I Research funding.

4.5 Study Budget.Institution represents that the Institution-provided Study budget upon which the D&I Research Support is based reflects an informed estimate of all funds required to complete and report the Study, including expenses relating to the publication of Study Results.

4.6 Disclosure by Pfizer. In the interest of transparency relating to its financial relationships with investigators and study sites or to ensure compliance with applicable local law, Pfizer may publicly disclose the support it provides under this Agreement. Institution agrees that Pfizer may disclose in any lawful manner the terms of this Agreement, the support or funding that Pfizer is providing under this Agreement, and any other related information, to the extent necessary for Pfizer to meet its obligations under those laws, regulations and industry codes that require Pfizer to report payments or other transfers of value to certain healthcare professionals and teaching hospitals (collectively, the "Transparency Laws"). Transparency Laws include, without limitation, section 6002 of the U.S. Affordable Care Act and the EFPIA Code on Disclosure of Transfers of Value.

a. Disclosure Content. In a transparency disclosure, Pfizer may identify both the Institution and the Principal Investigator, but will clearly differentiate between payments or other transfers of value to institutions and those made to individuals. Disclosures may include identifying information for institutions and

investigators, such as name, business address, specialty, National Provider Identifier (NPI), and licensure numbers.

b. Cooperation. Institution agrees to these disclosures on behalf of itself and its Principal Investigator. Institution further agrees to (and will cause Principal Investigator and other agents, employees and contractors to)reasonably cooperate with Pfizer in Pfizer's collection and disclosure of information to fulfill its Transparency Law obligations. Institution will provide Pfizer with complete and accurate information about payments or other transfers of value reportable under Transparency Laws.

5. Study Data and Study Results. For purposes of this Agreement, "Study Data" means the raw, non-aggregated data collected about each Study subject during the course of the Study. "Study Results" refers to aggregated or summarized Study Data and conclusions about the Study, as would be included in a study report or publication. Principal Investigator is free to publish the Study Results, subject to the provisions in Section 7 (Publications). In addition, a publication of Study Results may include such selected supporting Study Data as is reasonably required for purposes of publication in a scientific journal. Institution owns the Study Data and Study Results and Principal Investigator and Institution are free to use the Study Data and Study Results for any other purpose. Institution owns and is free to use the Study Data for their own research, educational and patient care purposes and programs. However, in consideration of the Pfizer D&I Support, Principal Investigator and Institution will not use or permit others to use the Study Data or Study Results for the commercial benefit of any third party, except to the extent that Institution is free to use Study Data as necessary to support applications for patents for an Invention even if such Invention may later be licensed to a third party.

6. Study Report. Within six (6) months after the Study Conduct Completion Date or termination of this Agreement, whichever occurs first, Principal Investigator will provide Pfizer with a written report of the Study Results ("Study Report"). Unless otherwise agreed in writing by the parties, the Study Report may take the form of a manuscript for publication (see Section 7, Publications), unless authorized representatives of the parties agree otherwise in writing. If the Agreement is terminated early, the Study Report should include, at minimum, the results of the Study up until the date of termination.

7. Publications. Pfizer supports the exercise of academic freedom and encourages Institution to publish the Study Results, regardless of the outcome. As used in this Agreement, "Publication" means materials or information resulting from the Study that are produced or released for dissemination to the public or in a public forum (whether or not under a confidentiality agreement), including but not limited to the following:

Submissions to peer-reviewed medical and scientific journals:
- o Primary and secondary manuscripts
- o Review articles
- o Letters to the editor
- o Brief communications
- o Supplements

Submissions to scientific congresses:

- o Abstracts
- o Posters
- o Presentations

Other:

- o Book chapters

7.1 Standards.For all Publications, Institution, Principal Investigator and all authors will comply with recognized ethical standards concerning publications and authorship, including the authorship guidelines in the Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals (http://www.icmje.org/icmje-recommendations.pdf) established by the International Committee of Medical Journal Editors and Section II - "Ethical Considerations in the Conduct and Reporting of Research" of the Uniform Requirements for Manuscripts Submitted to Biomedical Journals, http://www.icmje.org/index.html#authorship.

7.2 Disclosure of Support. Institution shall ensure that Principal Investigator and all authors disclose Pfizer support of the Study and their relationships with Pfizerin any Publication. More specifically, if any author receives financial compensation from Pfizer in connection with the development of a Publication, such author will disclose in the Publication that he/she was paid by Pfizer for the development of the Publication. If Pfizer paid for medical writing support for the Publication, the authors shall acknowledge, by name, the individuals who provided such support and disclose the funding sources for this assistance in the Publication.

7.3 Disclosure of Pfizer Funding to Other Organizations. Institution shall ensure the authors comply with all other applicable disclosure obligations they may have as a result of affiliation or membership of any committee, scientific organization, biomedical publishing enterprise, or health care institute.

8. Termination

8.1 Termination Events. Termination of this Agreement will be triggered by the earlier of any of the following events.

a. Completion of Agreement Obligations. The Agreement will terminate when the Study is completed, which means the completion of all Protocol-required activities for all enrolled subjects ("Study Completion"), and the parties have received all deliverables and payments owed.

b. Early Termination by Institution. If Institution terminates the Study early, for any reason, Institution may terminate the Agreement upon notice to Pfizer. Early Termination by Pfizer. Pfizer may terminate the Agreement early in any of the following circumstances:

1) The Protocol is modified in a way unacceptable to Pfizer (see Section 2.2, Amendments).

2) Study conduct is not completed within six (6) months after the target date (see Section 3.7, Duration of Study Conduct).

3) The Study does not start within six (6) months of the Effective Date of this Agreement.
4) Subject enrollment rate is significantly slower than that outlined in the Protocol or proposal or needed to complete the Study by the target date.
5) The Study design or objectives are no longer scientifically relevant.

c. Termination for Cause. Either party may terminate the Agreement immediately upon notification for cause, including but not limited to uncured material breach of the terms of this Agreement by the other party. Also considered adequate cause under this provision would be failure by Institution to comply with, or a demonstrated intent to fail to comply with, the warranties in Section 10 (Anti-Corruption).

8.2 Effective Date of Termination. If termination is triggered by events described in Sections 8.1.b or c above, termination will be effective after completion by both parties of any remaining applicable Agreement obligations.

8.3 Payment upon Early Termination. The terms in this Section 8.3, Payment upon Early Termination, apply only if the Agreement is terminated early for a reason other than for cause (see Section 8.1.d, Termination for Cause). Upon early termination, Pfizer will pay a pro rata portion of the total D&I Research Support,less payments already made. Institution will refund to Pfizer any funding already received in excess of this calculated amount except to the extent that such funds have already been used, or committed and unable to be canceled, in a manner consistent with the Study budget upon which the D&I Research Support is based or as prospectively approved by Pfizer.

8.4 Reconciliation upon Study Completion. At Study Completion, the parties will cooperate to perform a financial reconciliation to confirm consistency between total Pfizer milestone payments and the agreed-upon milestones and deliverables. The parties agree to make any adjustment (e.g., refund or additional payment) that is revealed by this analysis to be warranted.

9. Other Provisions

9.1 Indemnification. The Study is not designed, sponsored, or managed by Pfizer and Pfizer provides no indemnification of any type. Institution shall indemnify, defend, and hold harmless Pfizer and its affiliates, and its/their employees, contractors, agents, officers, and directors from and against any loss, liability, damage, cost, fine, penalty, or expense, including reasonable attorneys' fees, arising out of an audit, investigation, administrative proceeding, or litigation predicated upon Principal Investigator's or Institution's failure to provide complete and correct data pursuant to its data collection, submission and reporting obligations hereunder.

9.2 Debarment and Exclusion. Institution certifies that neither it nor Principal Investigator is debarred under subsections 306(a) or (b) of the Federal Food, Drug, and Cosmetic Act and that it has not and will not use in any capacity the services of any person debarred under such law with respect to services to be performed under this Agreement. Institution also certifies that both it and Principal

Investigator are licensed, registered, or otherwise qualified and suitable under local laws to act as a clinical study sponsor, study site, or investigator, as applicable. Institution further certifies that there are no applicable laws or other obligations that prohibit it from conducting the Study and entering into this Agreement. For U.S. sites, Institution also certifies that neither it nor Principal Investigator is excluded from any federal health care program, including but not limited to Medicare and Medicaid. Institution will notify Pfizer promptly if any of these certifications need to be amended in light of new information.

9.3 Affiliate. As used in this Agreement, the term "Affiliate" means any entity that directly or indirectly controls, is controlled by, or is under common control with the named party.

9.4 Law. As used in this Agreement, the terms "law" and "laws" should be understood to include all rules—local, national, regional, or international—that have binding legal force and effect and are prescribed, recognized, and enforced by a controlling governmental authority. Laws can include, but are not limited to, statutes, administrative regulations, treaties, and executive orders.

9.5 Personal Data. Information that could be used by itself or in combination with other available information to identify a specific individual is considered "Personal Data."

9.6 Processing of Personal Data by Pfizer. Pfizer uses global electronic systems for processing certain information in connection with D&I studies. These systems may include certain Personal Data provided to Pfizer by Institution that relates to persons who participate in or perform work in connection with the conduct of the Study. The Personal Data used in such systems generally includes information such as name, specialization, and contact information. Pfizer may transfer such Personal Data to Pfizer Affiliates, to Pfizer's research or business partners, to Pfizer-contracted service providers or consultants, or to relevant governmental authorities. Such recipients may be located outside the country in which the Study was performed, including the United States.

9.7 Entire Agreement. This Agreement (including Attachments) along with the referenced Pfizer-approved Protocol represent the entire understanding between the parties relating to this subject matter. This Agreement supersedes all previous agreements between the parties (oral and written) relating to this Study, except for any obligations that, by their terms, survive independent of this Agreement.

9.8 Conflict with Attachments or Protocol. If there is any conflict between this Agreement and any of its Attachments, the terms of this Agreement will control. If there is any conflict between the Agreement and the Protocol, the Agreement will control except with respect to medical, scientific, or clinical matters relating to Study conduct, for which the Protocol will take precedence.

10. Anti-Corruption

10.1 Definitions

a. Government. As used in this Agreement, "Government" includes all levels and subdivisions of governments (i.e., local, regional, and national; administrative, legislative, and executive).

b. Government Official. As used in this Agreement, "Government Official" includes (1) any elected or appointed non-US Government official (eg, 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 (eg, a healthcare professional employed by a non-US Government hospital or researcher employed by a non-US Government 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.

10.2 Warranties. Institution warrants to Pfizer the following:

a. Any information provided by Institution to Pfizer as part of Pfizer's anti-corruption due diligence process is complete and accurate.

b. The funding provided by Pfizer under this Agreement will not cause Institution or individuals affiliated with Institution to do anything that would result in Pfizer improperly obtaining or retaining business or gaining any improper business advantage.

c. Institution will not, and will take measures to ensure that individuals affiliated with Institution will not, use any portion of the Pfizer 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
   1) Pfizer to improperly obtain or retain business or to gain an improper business advantage, or
   2) Institution or the affiliated individual(s) to improperly obtain or retain business or gain a business advantage.

d. Neither Institution nor, to Institution's knowledge, any individuals associated with Institution have accepted a payment intended to improperly obtain or retain business for Pfizer or to gain an improper business advantage for Pfizer.

e. Institution will not, and will take measures to ensure that individuals associated with Institution will not, accept in the future any payment intended to improperly obtain or retain business for Pfizer or to gain an improper business advantage for Pfizer.

10.3 Non-Compliance. Failure to comply with, or a demonstrated intent to fail to comply with, any of the warranties in Section 10.2, above, will constitute adequate cause for Pfizer to immediately terminate the Agreement under Section 8.1.d, Termination for Cause. In such a circumstance, Pfizer is under no obligation to provide Institution an opportunity to cure before termination or to provide any further payment upon termination, including any payment for non-cancelable commitments by Institution relating to the Study.

11. Global Trade Control Laws. The Study covered by this Agreement may be subject to Global Trade Control Laws. Parties will perform the Study in full compliance with all applicable Global Trade Control Laws. For purposes of this Agreement, the term Global Trade Control Laws means all applicable import and export control laws, regulations, and orders, as well as all relevant economic sanctions laws, regulations, and orders. Institution acknowledges that the Study will not be in a Restricted Market or involve individuals, companies, organizations, or Governmental Entities from a Restricted Market. Institution represents and warrants that Institution is not a Restricted Party. With respect to the Study, Institution confirms that neither Institution nor its affiliates, agents, employees, or subcontractors directly or indirectly involved in the Study are Restricted Parties and that no Restricted Parties will be engaged in the Study or delegated any responsibilities to engage in the Study. In the event that any of the people or entities noted above, or any third party directly or indirectly engaged by such a person or entity, becomes designated as a Restricted Party during the Term of this Agreement, Institution will immediately inform Pfizer and suspend the Study until Pfizer agree to move forward. Notwithstanding any cure periods set forth herein, Institution acknowledges that designation of Institution or any other person or entity involved in the Studyas a Restricted Party, shall be grounds for immediate termination of this Agreement by Pfizer, for cause, with no cure period.If this Agreement is terminated for inclusion of a Restricted Party, Restricted Market, or Restricted Market national in the Studycovered under this Agreement without a license or other authorization required by Global Trade Control Laws or any other violation of Global Trade Control Laws, Pfizer shall not be responsible for any payments due to Institution or another Party, even if services have already occurred. Further, Institution and other Parties shall be responsible for reimbursing Pfizer for any payments due to Pfizer under this Agreement that are blocked due to inclusion of a Restricted Party, Restricted Market, or Restricted Market national in the Study covered under this Agreement without a license or other authorization required by Global Trade Control Laws or any other violation of Global Trade Control Laws."Global Trade Control Laws" include, but are not limited to, the U.S. Export Administration Regulations; the U.S. International Traffic in Arms Regulations; the economic sanctions rules and regulations implemented under statutory authority and/or President's Executive Orders and administered by the U.S. Department of the Treasury Office of Foreign Assets Control; European Union ("E.U.") Council Regulations on export controls, including Nos. 428/2009, 267/2012; other E.U. Council sanctions regulations, as implemented in E.U. Member States, United Nations sanctions polices; all relevant regulations and legislative instruments made under any of the above; other relevant economic sanctions, export and import control laws, and other laws, regulations, legislation, orders and requirements imposed by a relevant Governmental Entity. "Governmental Entity" or "Governmental Entities" 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."Restricted Market" or"Restricted Markets" means Crimean Peninsula, Cuba, Donbass Region, Iran, North Korea, Sudan (excluding South Sudan), and Syria."Restricted Party" or"Restricted Parties" means any individual(s) or entity(ies) on any of the Restricted Party Lists."Restricted Party List" or"Restricted Party Lists" means the list of sanctioned entities maintained by the United Nations; the Specially Designated

Nationals List and the Sectoral Sanctions Identifications List, as administered by the U.S. Department of the Treasury Office of Foreign Assets Control; the U.S. Denied Persons List, the U.S. Entity List, and the U.S. Unverified List, all administered by the U.S. Department of Commerce; the entities subject to restrictive measures and the Consolidated List of Persons, Groups and Entities Subject to E.U. Financial Sanctions, as implemented by the E.U. Common Foreign & Security Policy; the List of Excluded Individuals / Entities, as published by the U.S. Health and Human Services – Office of Inspector General; any lists of prohibited or debarred parties established under the U.S. Federal Food Drug and Cosmetic Act; the list of persons and entities suspended or debarred from contracting with the U.S. government; and similar lists of restricted parties maintained by the Governmental Entities of the countries that have jurisdiction over theStudy. "Restricted Party Screening" means the comparison of any individual or entity directly or indirectly involved in the Study, against the relevant Restricted Party Lists.

By accepting payment for this program from Pfizer, you certify to the representations set forth herein, and agree to abide by all requirements set forth herein.

Agreed to by:

PFIZER IGLC

_____ _____
AUTHORIZED REPRESENTATIVE **DATE**

_____
Printed Name

_____
Title

INSTITUTION

_____ _____
AUTHORIZED INSITUTION REPRESENTATIVE **DATE**

Prof. Francesco StagnoD'Alcontres

Chief of the Department of Human Pathology of Adulthood and Childhood "G. Barresi" of the University of Messina

Read and Acknowledged by:

_____ _____
PRINCIPAL INVESTIGATOR **DATE**

OanaRuxandra Cotta, MD, PhD

Attachment A
PAYMENT SCHEDULE

D&I Research Grant ID 34584263
TOTAL FUNDING AMOUNT: $75,000.00

NOTE: This Total D&I Funding Amount includes any overhead allowance.

Payments to be disbursed upon reaching the agreed upon milestones detailed below and updating the status in the Pfizer online Grant Management System (GMS).

Milestone Due Date	Description	Payment Amount	Payment Disbursed
-		Initial Payment	$45,000.00
February 1, 2018	Study status update report	$15,000.00	Ninety (90) days after submission
April 30, 2019	Final Payment upon receipt of Study Report due within six (6) months of Study Conduct Completion Date October 31, 2018	$15,000.00	Ninety (90) days after submission

Prior to each milestone, Institution/Principal Investigator will receive an email requesting the Institution/Principal Investigator to log into the GMS to enter the Study status update report and upload any relevant supporting documentation. Once the Study status update report (or Study Report following the project's completion) is reviewed and deemed to be complete by Pfizer, payment will be scheduled to be paid in 60 days (corporate payment terms). If upon review it is determined the milestone delivery has not been satisfactorily met as originally defined, Pfizer retains the right to modify the payment amount and/or scheduled disbursement date and future milestones as appropriate.

Initial Payment – Pfizer will make no initial payment until Pfizer has received (1) an executed copy of the Agreement and (2) the required documents identified in Attachment B, Study Documentation Requirements.

Final Payment – Pfizer will make the final payment only after receipt of the Study Report and completion of any applicable remaining obligations under the Agreement.

Attachment B

STUDY DOCUMENTATION REQUIREMENTS

- Executed D&I Research Agreement

- Final Protocol/Amendments

  Pfizer will not provide any D&I Research Support until after the receipt of the final Study Protocol. If the research described in the final Protocol is materially different from that in the approved proposal, Pfizer may choose to modify or withhold its Support.

  As indicated in the Agreement, the Principal Investigator must also promptly provide Pfizer with any amendments to the final Protocol approved by Pfizer. Continuation of D&I Research Support by Pfizer will be contingent on Pfizer's review and acceptance of these changes.

- IRB/IEC approval letters (initial approval and annual reviews, as applicable)

  For studies that require Institutional Review Board (IRB) or Independent Ethics Committee (IEC) approval of the final Protocol, Pfizer will not provide any D&I Research Support until after the receipt of a copy of the IRB/IEC approval letter.

  Continued D&I Research Support by Pfizer requires timely submission of documentation of annual renewal of this IRB/IEC approval.