



FLORIDA STATE UNIVERSITY

BOARD OF TRUSTEES

*University Research Committee*



# FLORIDA STATE UNIVERSITY

## BOARD OF TRUSTEES

### *University Research Committee*

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## MEETING AGENDA

Thursday, January 22, 2026

2:30 pm

Via Zoom

*The agenda will be followed in subsequent order and items may be heard earlier than the scheduled time.*

**I. Call to Order and Welcome**

*Trustee Jorge Gonzalez, Chair*

**II. Action Items for Consideration of Recommendation to the Board of Trustees**

*Dr. Stacey Patterson, Vice President for Research*

**Action Item I: Request for Approval:** Participation in a Research Consortium sponsored by the Novo Nordisk Foundation

**III. Open Forum for Trustees**

*Trustee Jorge Gonzalez, Chair*

**IV. Adjournment**

*Trustee Jorge Gonzalez, Chair*



FLORIDA STATE UNIVERSITY  
BOARD OF TRUSTEES  
*University Research Committee*

# ACTION ITEM I



# FLORIDA STATE UNIVERSITY

## BOARD OF TRUSTEES

### *University Research Committee*

#### **ACTION ITEM 1**

**January 22, 2025**

**SUBJECT: Request for Approval:** Participation in a Research Consortium sponsored by the Novo Nordisk Foundation

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#### **PROPOSED COMMITTEE ACTION**

Review and approve an exception to Section 288.860(3)(d) to participate in a consortium having a foreign principal member.

#### **AUTHORITY FOR BOARD OF TRUSTEES ACTION**

Florida Statute §288.860 and Board of Governors Regulation 9.012 include a requirement for Florida State University to obtain approval from the Board of Governors (BOG) of the State University System of Florida, following Florida State University Board of Trustees' approval, before accepting any grant from or participating in any agreement with any college or university based in a foreign country of concern, or with any foreign principal.

#### **BACKGROUND INFORMATION**

Florida State University seeks to participate in a potentially groundbreaking drug discovery study through a consortium sponsored by the Novo Nordisk Foundation. This project is anticipated to last three years and requires FSU's participation in the Gram-Negative Antibiotic Discovery Innovator Initiative (Gr-ADI).

To participate and receive funding, FSU Research Foundation must sign a Cooperation & Sharing Agreement, which represents an academic collaboration. While the Novo Nordisk Foundation (NNF) does not trigger the foreign country of concern (FCOC) regulation (Reg. 9.012), one member of the Gr-ADI consortium is the Beijing Huayi Health and Drug Research Institute (Global Health Drug Discovery Institute; GHDDI). Research security screening was completed and did not flag any participating entity or individual on a restricted party list.

The agreement is deemed to be valuable to FSU researchers and students and is not detrimental to the safety or security of the United States or its residents. The agreement provides mechanisms for control and protection of all FSU information and promotes the advancement open-science.

### **ADDITIONAL COMMITTEE CONSIDERATIONS**

Florida Board of Governors review and approval is needed following approval by the Florida State University Board of Trustees.

**Supporting Documentation Included:** BOT Submission-Novo Nordisk Foundation

**Submitted by:** Office of the Vice President for Research



State University System of Florida Board of Governors  
**REQUEST TO ENTER INTO ACTIVITY WITH A FOREIGN COUNTRY OF CONCERN**  
In accordance with Board of Governors Regulation 9.012  
(Please do not revise this proposal format without prior approval from Board staff)

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**Institution Submitting Request**

**Proposed Activity Type**

☐ **Agreement** (A written statement of mutual interest in academic or research collaboration)

☐ **Partnership** (Faculty or student exchange program, a study abroad program, an articulation program, a recruiting program, or a dual degree program)

☐ **Grant** (A transfer of money for a specified purpose, including a conditional gift)

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**Name/Title of Activity**

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**Name of Foreign Principal**

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**Location of Foreign Principal  
(Country)**

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**Expected Start Date of Activity**

*(Expected start date must not precede Board of Governor's approval date. Please allow ample time for the approval process. Contact Board staff if you have any questions regarding this.)*

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**Expected End Date of Activity**

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**The appropriate parties at the institution have approved the submission of this request. The university will not engage in the requested agreement, partnership, and/or grant prior to Board of Governor's approval.**

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**Date Approved by University Board of Trustees**

**Provost or Designee**

**Date**

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**Board of Trustee's Chair Signature      Date**

**President's Signature**

**Date**

Please review the below confidentiality statement before completing the form.

**Confidentiality Statement**

Per section 1004.22, Florida Statutes, materials that relate to methods of manufacture or production, potential trade secrets, potentially patentable material, actual trade secrets, business transactions, or proprietary information received, generated, ascertained, or discovered during the course of research conducted within the state universities shall be confidential and exempt from the provisions of section 119.07(1), Florida Statutes, except that a division of sponsored research shall make available upon request the title and description of a research project, the name of the researcher, and the amount and source of funding provided for such project.

**Description of Activity** (500 words maximum)

Please complete and submit the information below.

- A. Describe the proposed agreement, partnership, or grant under consideration within a few paragraphs, including the following information.
- The agreement's, partnership's, or grant's overall purpose
  - Expected benefits to the students and institution from the agreement, partnership, or grant
  - Any identified risks to the safety or security of the United States and its residents from the agreement, partnership, or grant

Please enter the description of the activity in this text box.

B. Complete the below table with as much applicable data as available for the agreement. When estimating the totals, please provide the total estimate for all years of the agreement or partnership as outlined on page 1 of this application.

|  |   |    |
|--|---|----|
| <b>Student &amp; Personnel Information</b> | <b>Number of Participating Students</b>   |    |
|  | <b>Number of Participating Institution Employees, Including Faculty</b>                   |    |
| <b>Financial Information</b>               | <b>Cost of the Agreement/Partnership/Grant to the Institution, if any</b>                 | \$ |
|  | <b>Amount of Research Funding to the Institution from the Agreement/Partnership/Grant</b> | \$ |
|  | <b>Source(s) of Funding</b>   |    |



## Florida State University

### Sponsor: Novo Nordisk Foundation

Florida State University, through the FSU Research Foundation (FSURF), seeks to participate in a potentially groundbreaking drug discovery study through a consortium sponsored by the Novo Nordisk Foundation. This project is anticipated to last three years and requires FSU's participation in the Gram-Negative Antibiotic Discovery Innovator Initiative (Gr-ADI).

To participate and receive funding, FSURF must sign a Cooperation & Sharing Agreement, which represents an academic collaboration. While the Novo Nordisk Foundation (NNF) does not trigger the foreign country of concern (FCOC) regulation (Reg. 9.012), one member of the Gr-ADI consortium is the Beijing Huayi Health and Drug Research Institute (Global Health Drug Discovery Institute; GHDDI). Research security screening was completed and did not flag any participating entity or individual on a restricted party list. Most parties of the consortium have signed the agreement including the Gates Foundation (GF), Wellcome Trust (WT), and several US universities. Therefore, FSU has been advised that no further adjustments are possible to the agreement.

Key considerations include:

1. Participation in this project is critical to advance drug discovery and translational and data-driven biomedical research, a stated priority area for FSU.
2. The project advances open-science (i.e. open sharing of publications, datasets, metadata or code to support the production of open knowledge) and provides Florida faculty and students access to globally benchmarked datasets, **without** personnel exchange or joint IP ownership.
3. Participation does not require the sharing of confidential data (e.g., compound structures).
4. There is no transfer of controlled technologies.
5. Data are shared exclusively through open repositories. Gr-ADI consortium members share progress updates and results with other members at workshops and meetings.
6. No personnel from a FCOC would access Florida systems.
7. Existing members are given an opportunity to object to the addition of any prospective new members on the basis it would be detrimental to the Gr-ADI initiative. Objecting members may share their concerns with the Funders (NNF, GF, and WT).
8. The agreement states its terms shall not require a member to act in contravention of any applicable laws and regulations, including but not limited to those relating to national security, export controls or sanctions. Should such a compliance concern arise impacting a member's ability to conduct consortium activities, the affected member is to notify Funders to discuss, to the extent legally permitted.

### Project Summary:

Antibiotic resistance is a growing global health problem, especially among bacteria such as *Klebsiella pneumoniae*, which are increasingly difficult to treat with existing drugs. This project aims to discover new antibiotics by developing a faster, more efficient discovery process. The research proposal presents an ultra-high-throughput antibiotic discovery pipeline to identify novel natural products (NPs) effective against multidrug-resistant *Klebsiella pneumoniae*.

The approach focuses on soil bacteria, which have long been a major source of antibiotics. However, most of their natural drug-producing genes remain inactive under normal lab conditions and therefore undiscovered. This project will use advanced micro-scale technology to "turn on" these hidden genes and test the resulting compounds for antibacterial activity. The new system would allow thousands of tests to be run at once, much faster than traditional methods, and would also screen early for potential drugs' safety in

human cells. This combined process is designed to reduce wasted effort on toxic or already known compounds and to speed up the search for entirely new antibiotics.

The project relies on several unique assets within Florida State University, including soil collection, custom-built microfluidic devices, and the FT-ICR Mass Spectrometer at the FSU MagLab. **These resources will not be shared under the Data Sharing and Collaboration Agreement and will not be accessible to any foreign individuals as part of this project.**

The central discoveries in this project (the microbial strains that produce antimicrobial compounds and the structures of those compounds) will be treated as confidential information. The microbial strains are not required to be shared, and the compound structures are similarly not required to be shared under the terms of the agreement.

| <b>Institution</b>  |
|---|
| <b>Legal Entity (Common name, if different) [Abbreviation]</b>                                      |
| The Chancellor, Masters, and Scholars of the University of Oxford (University of Oxford) [UO]       |
| Imperial College of Science, Technology and Medicine (Imperial College London) [ICL]                |
| Northeastern University [NEU]   |
| Tufts University [TU]   |
| The Board of Regents of the University of Wisconsin System (University of Wisconsin) [UW or UWS]    |
| National University Corporation Nagasaki University (University of Nagasaki) [NU]                   |
| Stellenbosch University [SU]  |
| Beijing Huayi Health and Drug Research Institute (Global Health Drug Discovery Institute) [GHDDI]   |
| The Board of Trustees of the University of Illinois (University of Illinois) [UI]                   |
| The Chancellor, Masters, and Scholars of the University of Cambridge (Cambridge University) [CU]    |
| Laboratório Nacional de Computação Científica (National Laboratory for Scientific Computing) [LNCC] |
| The Francis Crick Institute Limited (The Francis Crick Institute) [Crick]                           |
| The Scripps Research Institute (Calibr-Skaggs Institute for Innovative Medicines) [Calibr]          |
| University of Ghana [UG]  |
| University of Cape Town (H3D) [H3D]   |
| University of Connecticut [UConn]   |
| Vlaams Instituut voor Biotechnologie (VIB) VZW [VIB]  |
| Université de Montréal [UdeM]   |
| University of Dundee [UoD]  |
| University of Washington [UW]   |
| President and Fellows of Harvard College (Harvard University) [HU]                                  |

## COOPERATION & SHARING AGREEMENT

### Gram-Negative Antibiotic Discovery Innovator Initiative

THIS COOPERATION & SHARING AGREEMENT (this Agreement) is hereby entered into effective as of [ \_\_\_\_\_, 20\_\_] by and among the initial members of the Gr-ADI listed in Annex A (each a Party and a Gr-ADI Member and collectively the **Parties and the Gr-ADI Members**).

WHEREAS, each Party is a participant in the Gram-Negative Antibiotic Discovery Innovator (**Gr-ADI**) – an initiative delivered by the Gates Foundation (**GF**), the Wellcome Trust (**WT**), and the Novo Nordisk Foundation (**NNF**) (collectively, the **Funders**) to catalyze early-stage antibiotic discovery, particularly focusing on carbapenem-resistant Enterobacteriaceae (CRE) (including *Klebsiella spp.* and *Escherichia coli*). Each Party becomes a Gr-ADI Member upon their signature of this Agreement.

WHEREAS, each of the Parties acknowledge that the goal of the Gr-ADI is to enable discovery of safe and simple first-line broad-spectrum drugs for syndromic management, through (i) development of novel and emerging biological, chemical, and AI tools that can be applied broadly for antibiotic discovery to identify new antibiotic targets; (ii) application of these innovative approaches to generate chemical starting points for project-based drug discovery, and (iii) fostering a collective mindset to address gaps in knowledge, solve problems, and manage a portfolio of targets and hits (the **Gr-ADI's Goal**).

WHEREAS, the Gr-ADI is not a separate legal entity and this Agreement and its Annexes do not themselves create an obligation on Gr-ADI Members to contribute resources or undertake research projects, but this Agreement and its Annexes do create a collaborative framework through which Gr-ADI Members may better collaborate in support of the broader Gr-ADI initiative whilst carrying out their individual research projects.

WHEREAS, the Gr-ADI Members intend to work in collaboration, united by a robust system for the exchange of Data and Materials, and supported, as appropriate, by Funders' staff and a central Gr-ADI Programme Manager.

WHEREAS, the agreements needed to establish the Gr-ADI as a working collaborative network will be based on this Agreement and the Annexes hereto.

WHEREAS, each of the Parties agrees to conduct Gr-ADI Projects under this Agreement in a manner that is consistent with and in furtherance of Global Access Objectives.

Now, therefore, the Parties agree to the following terms and conditions:

1. **Defined Terms.** Annex B contains a set of defined terms that have the same definition as used within this Agreement and the documents described in Sections 4-6 below, unless otherwise specifically stated in the particular document.
2. **Cooperative Activities.** The Parties agree to use good faith efforts to conduct various activities under the Gr-ADI in a collaborative fashion with other Gr-ADI Members with the aim of accelerating the achievement of the Gr-ADI's Goals through the building of efficiencies, avoiding

redundancies and cross-analyzing research results. Save as set out in any individual funding agreement between a Funder and a Gr-ADI Member, and the terms of this Agreement, the scope, timing and level of such cooperative activities, and the budgetary implications, in are to be agreed upon by the organizations conducting the activities. The Parties shall share with other Gr-ADI Members all material Gr-ADI developments including: progress updates, new basic scientific findings about bacteria and/or resistance, information relating to identified targets, and details of and access to all Gr-ADI funded models, tools and techniques under development in accordance with Annex C. Additional, specific, cooperative activities may be identified and suggested by any Gr-ADI Member, the Funders or the Scientific Advisory Group of Experts. This agreement does not prohibit Gr-ADI Members from collaborating with non- Gr-ADI Members in projects related to Gram-negative drug discovery.

3. **Other Bodies (Scientific Advisory Group of Experts & Programme Manager).** A Scientific Advisory Group of Experts (SAGE) will be established by the Funders to provide guidance to the Gr-ADI Members in the performance of Gr-ADI Projects and to the Gr-ADI as a whole in order to identify priorities, potential cooperative activities and possible additional organizations to be included in the Gr-ADI, assessing ongoing work and shaping the overall direction of the Gr-ADI. Furthermore, the Funders anticipate appointing a third party to support Gr-ADI by acting as a Programme Manager, who will (at least) facilitate communications across the Gr-ADI initiative, coordinate progress reporting, and identify further cooperation and sharing opportunities. All Gr-ADI Members will share data and otherwise cooperate with SAGE and the Programme Manager, as reasonably required by them from time to time to perform their respective functions.

4. **Guiding Principles for Sharing.** In furtherance of the primary goals of the Gr-ADI, and taking into consideration and balancing the respective business, legal and academic needs and incentives, the Parties have prepared the Data & Materials Sharing Guiding Principles as set out in Annex C. Each Party hereby agrees that they will comply with the Guiding Principles regarding its sharing of Data and Materials with the other Gr-ADI Members and the broader scientific community.

5. **Confidentiality.** Each Party hereby agrees that Confidential Information exchanged between Gr-ADI Members shall be exchanged in accordance with the terms of the Master Gr-ADI Confidential Disclosure Agreement set out in Annex D. Each of the SAGE Members and the Programme Manager will be appointed by the Funders under terms which require them to keep all unpublished disclosures to them as confidential within the Gr-ADI Initiative and to only share and use such disclosed information for the purpose of advancing Gr-ADI in a manner broadly consistent with the terms of Annex D. The same applies to disclosures between the Funders. Therefore, Annex D does not apply, and separate transfer record forms are not required, for any Party's disclosures to SAGE Members, the Programme Manager and the Funders.

6. **Material Transfers.** Each Party hereby agrees that Materials which are transferred between Gr-ADI Members shall be transferred in accordance with the terms of the Master Gr-ADI Material Transfer Agreement set out in Annex E.

7. **Incorporation by Reference; Modification.** All Annexes and Exhibits referenced above are hereby incorporated into and made a part of this Agreement. This Agreement may only be modified or supplemented in a writing expressly stated for such purpose and signed by the Parties.

8. **Counterparts.** This Agreement may be signed in counterpart, each of which will be considered an original, and all of which collectively will be deemed the same document.

9. **Affiliates.** Each Gr-ADI Member shall have the right to extend the rights and licenses granted to it hereunder to those entities which can be defined as such Gr-ADI Member's Affiliates, provided that such Gr-ADI Member shall remain responsible and liable for all obligations of its Affiliates under this Agreement.

10. **Gr-ADI Membership.**

(a) All initial Gr-ADI Members are Gr-ADI Members upon their signature of this Agreement. From time to time as the Funders wish to issue new Gr-ADI awards (necessitating the admission of new Gr-ADI Members), or otherwise add new Gr-ADI Members, the Funders will notify the then existing Gr-ADI Members. Each existing Gr-ADI Member will then have 14 days in which to notify the Funder(s) if they object to such admission, which shall only be on basis that it would be detrimental to the Gr-ADI initiative. Any objecting Gr-ADI Member(s) agrees to then promptly discuss their concerns with the Funders and to work constructively with the Funders in good faith to resolve those concerns such that the new award can be issued and/or the proposed new Gr-ADI Member added. If no objection is received in that time, the new party will be admitted when they sign this Agreement.

(b) Neither the signature, nor the consent, of existing Gr-ADI Members is required in order for new Gr-ADI Members to join this Agreement and each Gr-ADI Member hereby agrees to treat all new joining Gr-ADI Members as Parties to this Agreement as from the date the joining Gr-ADI Member signs this Agreement, or such other effective date as the joining Party agrees with the Funder(s). Details of newly admitted Gr-ADI Members, together with summaries of their projects or other anticipated contributions, will be shared by the Funder(s) and/or the Programme Manager with the existing Gr-ADI Members for information purposes from time to time.

(c) A Gr-ADI Member may withdraw from this Agreement, provided such Gr-ADI Member is not subject to an active funding agreement, upon written notice to the relevant Funder(s). The withdrawal of a Gr-ADI Member will be effective 60 days following the receipt of such notice.

(d) In the event a Gr-ADI Member is unable or unwilling to continue to make a material contribution to the Gr-ADI Goals, it may be invited by the Funders to withdraw their membership in the Gr-ADI in accordance with sub-paragraph (c).

(e) Withdrawal under sub-paragraph (c) or (d) or expiration of this Agreement under Section 11 below does not affect any rights or obligations established (including license rights granted to and by the withdrawing or terminated Gr-ADI Member) with respect to Gr-ADI Inventions, Data, Materials, Confidential Information, or obligations to achieve the Global Access Objectives established prior to the effective date of the withdrawal.

(f) Gr-ADI Members will be required to acknowledge the Gr-ADI funding in relevant publications and when making funded outputs available. Gr-ADI Members shall notify the Funders of any follow-on funding received from other sources for the purpose of further progressing any Gr-ADI Project. If requested, Gr-ADI Members shall provide impact reports, to help the Funders assess the success of Gr-ADI. Impact reports may include, for example, details of Gr-ADI related publications, and Gr-ADI Members who developed leads with Gr-ADI funding may also be asked to report on material developments (including patent filings) should development of those leads progress.

(g) Gr-ADI Members are required to attend and actively participate in relevant consortium workshops and events, as well as through more informal ad-hoc interactions and working groups. One purpose of such meetings will be to identify specific ways in which consortium members can share learnings, support each other, and collaborate to meet the goals of Gr-ADI.

11. **Term.** This Agreement shall remain in force as long as there are at least two Gr-ADI Members.

12. **Compliance with Laws.** In conducting its activities under this Agreement and the Annexes hereto, each Gr-ADI Member agrees to comply with all applicable laws and regulations, including but not limited to the antitrust and/or competition laws of governing jurisdictions. For the avoidance of doubt, nothing in this Agreement shall require a Party to act in contravention of any applicable laws and regulations, including but not limited to those relating to national security, export controls or sanctions. Should such a compliance concern arise impacting a Party's ability to conduct Gr-ADI activities, the affected Party shall notify the Programme Manager and Funder(s) to discuss, to the extent legally permitted to do so.

13. **No Conflict.** Agreements entered into or obligations assumed by Gr-ADI Members prior to signature of this Agreement (or that will be entered into or assumed thereafter) do not and will not prohibit or prevent the Gr-ADI Member from performing its obligations under this Agreement and the Annexes hereto.

14. **Publicity.** Gr-ADI Members agree that they may publicize the fact of the existence of the Gr-ADI, their membership and descriptions of the Gr-ADI in a manner consistent with this Agreement and any related Funder agreement. No Party, may, however directly or indirectly cause or permit the use of any Party's name, trade name, logo or trademarks without such Party's prior written consent.

15. **Programme Manager.** Gr-ADI Members agree that a programme manager will be appointed by the Funders (the **Programme Manager**). The Programme Manager will have the responsibility of supporting the work of the Gr-ADI.

17. **Non-Debarment Certification.** Each Gr-ADI Member certifies that as of the date of its receipt of Materials hereunder that neither it and or any of its employees or principals performing any acts in connection with the handling or use of the Materials is debarred, suspended, or proposed for debarment by the U. S. Food and Drug Administration ("FDA") or any agency of the U.S. Federal Government or any foreign and applicable equivalent of the FDA ("Applicable Governmental Authority"). Further, each Gr-ADI Member shall provide immediate written notice to the Provider of any materials in the event that such Gr-ADI Member or any of its employees or principals is debarred, suspended, or proposed for debarment by the FDA or an Applicable Governmental Authority.

**SIGNATORY**  
**to the**  
**Gr-ADI COOPERATION & SHARING AGREEMENT**

IN WITNESS WHEREOF, the undersigned Party hereby executes the Gr-ADI Cooperation & Sharing Agreement.

\_\_\_\_\_

By: \_\_\_\_\_

Name: \_\_\_\_\_

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

Date Signed: \_\_\_\_\_

***[Separate Signature Pages to be Completed by Each Gr-ADI Member]***



**ANNEX A**  
**Initial Gr-ADI Members**

## ANNEX B DEFINITIONS

**Affiliate** means any business entity controlled by, controlling or under common control of a Gr-ADI Member. Such control shall include beneficial ownership of more than fifty percent (50%) of the voting interest in an entity, or such other relationship as, in fact, constitutes actual control.

**Assays** means any assays performed in the conduct of any Gr-ADI activities including, but not limited to, MIC determination, MBC determination, kill kinetics, in vitro PK/PD modeling, synergy screening, microbiological spectrum, frequency of resistance, cross-resistance, mechanistic assay, biochemical or biophysical tests, safety assessment or *in vivo* test.

**Compound Structure Data** means the precise chemical structure of the compound, including full stereochemical representation.

**Compound Related Data** means data and information (but excluding Compound Structure Data) specific for the compound, including but not limited to activity in biological assays and predicted and/or measured physiochemical and biological properties.

**Confidential Information** has the meaning as provided in the Master Gr-ADI Confidential Disclosure Agreement.

**Data** means recorded information, tools and models generated in the performance of a Gr-ADI Project, including (but not limited to) Compound Related Data and the interpretation and analysis of results, and associated opinions, from the performance of any assays conducted in furtherance of Gr-ADI-related activities, provided, however, the term Data shall not include “Compound Structure Data.”

**Global Access Objectives** means (i) the prompt dissemination of new scientific information within the Gr-ADI and with the broader scientific community and (ii) that any entity commercialising a new antibiotic developed from a Gr-ADI-funded lead compound considers the most appropriate ways in which to provide responsible stewardship of, and equitable access to, the new product once it reaches the market to people most in need within low- and middle-income countries.

**Guiding Principles** means the Data & Materials Sharing Guiding Principles as described in Section 4 (and contained in Annex C) of the Gr-ADI Cooperation & Sharing Agreement

**Hit** means a compound that has been screened within one or more hit-finding assays of the Gr-ADI, identified as active based on appropriate hit-calling criteria, and for which relevant biological activity (target based and/or phenotypic), purity, and structure have been confirmed.

**Identified Pathways** means the biochemical or metabolic pathways by which a chemical entity affects antibiotic activity.

**Identified Target** means the biochemical target (e.g. enzyme, protein, macromolecule, etc.) by which a validated chemical hit manifests its antibiotic activity.

**Lead Series** means a chemical series which (i) a Gr-ADI member has, at its sole discretion, determined to be unencumbered by internal or external obligations, and (ii) the Gr-ADI Member deems to have met the following criteria, to be more specifically defined as project-specific compound progression criteria: (a) Series demonstrates discrete, reasonable structure-activity relationship (SAR) (b) Series passes holistic analyses of series properties, including chemical and metabolic stability, reactivity, toxicity, selectivity, etc., (c) Series risks have been explored and defined (genotoxicity, in vitro and in vivo metabolism, drug-drug interactions, etc.), and (d) the series is deemed “chemically tractable/druggable” and judged to have potential to afford a preclinical drug candidate.

**Materials** – means physical materials for use in any Gr-ADI Project, including but not limited to, compounds, bacterial strains (e.g., resistant mutants, knockdown strains, over-expression strains), DNA, plasmids, Progeny, or other reagents. For purposes of this definition Progeny means unmodified descendants from the original Materials (as described in the specific Gr-ADI MTA document being used to transfer the Materials).

**Protocol/SOPs** means a detailed written description of an experimental procedure which will enable other researchers to accurately replicate assays, models, tools and methods within their laboratories.

**Publish or Publishing** means the act of communicating to the public, whether through publications, presentations, posters or otherwise, and whether by text or images via written, verbal or electronic means (with such means being referred to collectively as **Publications**).

**Gr-ADI** means a network of Gr-ADI Members largely funded by the Funders, to support the implementation of the scientific strategic plan of the Gram-Negative Antibiotic Discovery Innovator Initiative.

**Gr-ADI Invention** means any invention or discovery of any new and useful process, machine, manufacture or composition of matter or any new and useful improvement thereof, conceived and reduced to practice by Gr-ADI Members pursuant to the activities of the Gr-ADI.

**Gr-ADI Master CDA** means the Master Gr-ADI Confidential Disclosure Agreement as described in Section 5 of the Agreement (and contained in Annex D).

**Gr-ADI Member** means an institution that has agreed in writing to this Gr-ADI Data & Materials Sharing Agreement.

**Gr-ADI Master MTA** or Master MTA means the Master Gr-ADI Materials Transfer Agreement as described in Section 6 of the Agreement (and contained in Annex E).

**Gr-ADI MTA** means all of the agreement terms, including the provisions of the Gr-ADI Master MTA, governing the individual transfer of Materials from one Gr-ADI Member to another Gr-ADI Member.

**Gr-ADI Projects** means the Gr-ADI-related data and material sharing activities and collaborative research project established and conducted by Gr-ADI Members and specifically excludes projects that Gr-ADI Members are pursuing on their own or with third parties who are not Gr-ADI members.

## ANNEX C

### DATA & MATERIALS SHARING GUIDING PRINCIPLES

#### Gram-Negative Antibiotic Discovery Innovator Initiative

The conduct of Gr-ADI projects, and the sharing of information and materials in accordance with these data sharing principles, will be in a manner consistent with and in furtherance of the Global Access Objectives.

#### 1. DATA SHARING PRINCIPLES

##### a. Definitions

Capitalized terms not otherwise defined in these Guiding Principles shall have the definitions as provided to them in Annex B to the Gr-ADI Cooperation & Sharing Agreement.

##### b. Inventions

- i. Ownership of Gr-ADI Inventions is outside the scope of these Guiding Principles and should be addressed by the Gr-ADI Members concerned under separate contractual arrangements and under the appropriate laws governing inventorship and ownership of inventions.
- ii. To the extent not prohibited by law, regulation or third-party obligation (which obligation exists prior to the organization becoming a Gr-ADI Member), each Gr-ADI Member agrees to grant to the other Gr-ADI Members a fully paid-up, worldwide, non-exclusive, royalty free license to make and use all Gr-ADI Inventions for purposes of education and research within the activities of the Gr-ADI. To the extent such grants by a Gr-ADI Member are prohibited by law, regulation, or pre-existing third-party obligation, the relevant Gr-ADI Member will in good faith seriously consider requests from Gr-ADI Members for a license to such Gr-ADI Inventions for such purposes and explore ways to enable such use on similar terms. The grant of the right to make and use provided under this paragraph does not waive any obligations under the Gr-ADI Master CDA, the Gr-ADI Master MTA, or other contractual arrangement between the Gr-ADI Members.

### **c. Management of Data**

- i. The ownership of Data is outside the scope of these Guiding Principles and should be addressed by the Gr-ADI Members under a separate contractual arrangement.
- ii. The Funders, in consultation with the Gr-ADI Members, will identify a data repository or database, its functionality (including levels of confidentiality, and levels of disclosure) and the types and timing of Data to be deposited and timeline for public disclosure, all of which will be constructed and operated in a manner that is consistent with the terms of these Guiding Principles.
- iii. In the event a data repository or database is constructed or identified for use within the Gr-ADI, no organization (including the Funders) shall assert against any Gr-ADI Member or the Funders any database rights, copyrights, moral rights or other rights in the Data incorporated into such repository or database to the extent it is being utilized to support the primary objectives of the Gr-ADI. For the purpose of clarity, nothing in this section affects ownership of such rights or the ability to assert those rights if used outside the identified range of parties and uses.

### **d. Confidentiality of Information**

Subject to the provisions contained in these Guiding Principles, Confidential Information (as defined in the Gr-ADI Master CDA), including but not limited to Data, that is shared between Gr-ADI Members will be held in confidence according to the terms of a Master Gr-ADI CDA.

### **e. Treatment of Data**

- i. The Gr-ADI Members will work with the Funders to:
  1. Determine the process by which Data will be physically or electronically transferred among the Gr-ADI Members.
  2. Establish data standards for each Gr-ADI Project to the extent helpful to facilitate the sharing and comparison of Data and information required herein, and shall take into account applicable laws and regulations.

ii. The following specific types of Data generated by a Gr-ADI Member in the performance of a Gr-ADI Project and specifically related to antibiotics will be treated in the manner described below and all Data and information that is shared or made available will be in the form of robust, reproducible datasets which would meet commonly accepted scientific standards:

1. All such Data relating to Assays and Protocols/SOPs shall be readily shared amongst other Gr-ADI Members upon request. In addition, this Data should be made available to the broader scientific community within a prescribed time (determined by the Funders ), ideally as soon as possible but at the latest within 18 months of Data generation and no later than 6 months from completion of the project.
2. Data comprising A.I. and Machine Learning tools must be promptly shared with Gr-ADI Members. In addition, such tools should be made available to the broader scientific community within a prescribed time (determined by the Funders), ideally as soon as possible but at the latest within 18 months of the tool's production. In each case, if such tools were trained using proprietary datasets, while they must still be made freely available, controls may be placed on the access to, and the use of, such tools to the extent necessary to prevent the disclosure of the proprietary training data in question.
3. All such Data associated with Identified Targets shall be readily shared amongst other Gr-ADI Members upon request. In addition, this Data should be made available to the broader scientific community within a time prescribed by the Funders, ideally as soon as possible but minimally within 18 months of Data generation and no later than 6 months from completion of the project.
4. All such Data associated with Identified Pathways shall be readily shared amongst other Gr-ADI Members upon request. In addition, this Data should be made available to the broader scientific community within a time prescribed by the Funders, ideally as soon as possible but minimally within 18 months of Data generation and no later than 6 months from completion of the project.
5. Such Data associated with Hits (other than Compound Structure Data) shall be shared amongst other Gr-ADI Members; provided, however, information relating to the performance characteristics of the primary screen (number of compounds screened or percentage of such compounds active in the screen, number or percentage active at different cut-offs, etc.) shall be shared with all the Gr-ADI Members as promptly as possible.
6. Subject to Sections 1-5 above, all such Data relating to Lead Series will be shared with the other Gr-ADI Members as promptly as possible. All such Data that represents cumulative learnings from activities by a single Gr-ADI Member (e.g., analysis and synthesis of information derived from Data relating to Hits) will be shared with the other Gr-ADI Members as promptly as possible, subject to a reasonable (but as brief as possible) delay to allow

for the filing of a patent application should patent protection be desired at this stage. Such Data will thereafter be made available to the broader scientific community within 36 months following its being made available to other Gr-ADI Members, provided that any such proposed publication is subject to Annex C, Clause 3 – “Publication”. This timeline may be extended as reasonably required if the Lead Series is the subject of an active Gram-negative antibacterial drug discovery program and additional time is required to pursue patent protection pertaining to that program.

7. For the purposes of clarity, Data that is shared with other Gr-ADI Members in accordance with this Section 1e.ii. is considered Confidential Information unless or until it falls within the scope of Section 5 of the Master CDA or is otherwise allowed to be shared with non-Gr-ADI members under the terms of the Agreement or its Annexes. But in the event of a conflict between the terms of these Guiding Principles and the Master CDA or the Master MTA, the provisions of these Guiding Principles shall take precedence.
  8. Gr-ADI Members will use all reasonable efforts to promptly submit journal articles arising from their Gr-ADI activities (which at the latest shall be within 12 months of the completion of the relevant Gr-ADI Project) and to support timely submission and publication of such articles when they are named as co-authors.
- iii. Any other Data generated by a Gr-ADI Member in the performance of a Gr-ADI Project, and any Data used by a Gr-ADI Member in the performance of a Gr-ADI Project, will be shared by such Gr-ADI Member if such Data would be reasonably useful to other Gr-ADI Members in the performance of Gr-ADI Projects.
  - iv. For Hits that meet Lead Series criteria, the Gr-ADI Cooperation & Sharing Agreement does not mandate the disclosure of Compound Structure Data to Gr-ADI Members. Likewise, the Gr-ADI Cooperation & Sharing Agreement does not prohibit the disclosure of Compound Structure Data for Lead Series, at the sole discretion of the Gr-ADI Member generating the compound, in accordance with the Gr-ADI Master CDA. The Funders and Gr-ADI Members may develop and implement additional principles and practices to govern the sharing of Compound Structure Data to facilitate its use within a Gr-ADI Project.
  - v. In general, for Hits that do not meet Lead Series criteria, associated Compound Structure Data may be optionally kept private by a Gr-ADI Member except when the compounds:
    - (a) have been publicly disclosed as having relevant target-based or phenotypic activity; or (b) have been entered into mode of action studies for their Gram-negative activity or other research activities in Gram-

negative antibiotic discovery by the Gr-ADI Member (whereupon it shall be made available to other Gr-ADI members within 6 months of entering mode of action studies or other research activities, and to the broader scientific community within 36 months of entering such studies).

## **2. MATERIALS SHARING PRINCIPLES**

- a.** Each Gr-ADI Member acknowledges that it is strongly encouraged to share Materials among other Gr-ADI Members, but is under no obligation to do so. The Gr-ADI Members also acknowledge that their ability to share Materials may be limited for various reasons, including the availability of the Materials. The Gr-ADI Master MTA shall define the terms, including the authorized use, of the transfer of Materials for use within a Gr-ADI Project.
- b.** Ownership of Materials is outside the scope of these Guiding Principles and should be addressed by the Gr-ADI Members under the relevant Material Transfer Record Form attached to the Gr-ADI Master MTA, along with any need for confidentiality of information concerning the Materials.
- c.** Consistent with the strong encouragement of sharing, Gr-ADI Members shall use good faith efforts to treat Materials that are generated from or used within their work on generating lead compounds in the following manner:
  - i.** Bacterial strains shall be made available to other Gr-ADI Members upon request subject to applicable laws, regulations and restrictions.
  - ii.** Hits and Lead Series shall be made available to other Gr-ADI Members upon request, minimally on a “blinded” basis (without sharing Compound Structure Data), both according to agreements between the two parties and in accordance with the principles outlined within this document.
  - iii.** Other biological reagents and tools, including plasmids, etc., shall be made available to other Gr-ADI Members upon request.
  - iv.** In general the recipient shall bear the costs associated with preparing and shipping the materials.
- d.** The Gr-ADI Members will, on a semi-annual basis, provide a list of relevant Materials that are potentially available for use by the Gr-ADI Members. The Funders will establish the mechanism for creating and updating a consolidated list of such Materials.

## **3. PUBLICATION RIGHTS**

Subject to the provisions of Sections 1 and 2 above, Data will be Published according to the following principles:

- a.** With respect to all Data generated by a Gr-ADI Member (Recipient) in conducting activities using Materials that it received from another Gr-ADI Member (Provider), the individual



Gr-ADI Member(s) of the Provider may Publish on that Data accompanied by the appropriate attributions (co-authorship or acknowledgement as appropriate, in accordance with authorship guidelines referenced below where Publication is in written form) of the relevant Gr-ADI Member (Recipient) that contributed to the generation of the Data. The individual Gr-ADI Member(s) of the Recipient that generated the Data may also Publish on such Data. The Party desiring to publish on Data shall furnish the Provider or Recipient, as the case may be, with a copy of any proposed Publication for review and comment at least forty-five (45) days prior to submission for publication and shall reasonably consider any comments provided and requested amendments to the text to protect Confidential Information, in particular through its removal. However, nothing herein shall be interpreted to require the publishing Party to delete or alter the Data and conclusions of the study in any publication. If during the review period, the Provider notifies the publishing Party that it desires to establish a patent filing strategy, to accommodate filing patent applications on disclosed inventions, publishing Party will defer publication or other disclosure for a period, not to exceed an additional forty-five (45) days, sufficient to permit the Provider or its designee to have filed or to file any desired patent applications. At the end of the review period, the publishing Party will have the right to proceed with the publication.

- b. With respect to all Data generated jointly through cooperative activities among multiple Gr-ADI Members, all associated Gr-ADI Members will have the joint right to Publish on such Data, subject to Section 3.a., above. In this case, the Gr-ADI Member that intends to Publish shall furnish the other applicable Gr-ADI Members (including the Gr-ADI Member (Provider)), with a copy of any proposed Publication for review and comment at least forty-five (45) days prior to submission for publication and shall reasonably consider any comments provided and any requests for a short delay in publication to accommodate filing patent applications on disclosed inventions. Such a short delay may be extended for an additional forty-five (45) day period by the Gr-ADI Member concerned where necessary to have adequate time to file patent applications on disclosed inventions. Moreover, the Member that intends to Publish shall ensure that the Publication of the Data is accompanied by the appropriate attributions (co-authorship or acknowledgement as appropriate, in accordance with the authorship guidelines referenced below) for each of the applicable Gr-ADI Member.
- c. Authorship guidelines will be in accordance with those of the International Committee of Medical Journal Editors, or other generally recognized standards.
- d. Any dispute relating to Publications will be referred to the Funders for resolution, with input from the SAGE as requested by the Funders.

#### 4. NON-Gr-ADI MEMBERS

- a. Involvement in Gr-ADI Activities. The Parties agree that broad involvement in the activities of the Gr-ADI will be beneficial in building and sustaining a robust environment of collaborative research aimed at furthering the Gr-ADI's primary objectives. In the event an organization outside the Gr-ADI wishes to conduct Gr-ADI related activities in conjunction with a Gr-ADI Member and/or utilize Materials (e.g., compounds) or other resources (e.g., Funder funded reagents or screens), the Funders will establish a process whereby the anticipated work and Materials (including without limitation third party compounds to be screened) will be confidentially evaluated to assess whether there would be any redundancy relative to the ongoing work within the Gr-ADI.

- b. Sharing of Gr-ADI Inventions & Materials . Where Gr-ADI Inventions and/or Materials that are generated or identified through the activities of a Gr-ADI Project are shared with a third party organization (i.e., outside the Gr-ADI Members), such sharing can only be undertaken with the permission of the Gr-ADI Member that is the provider of such Gr-ADI Inventions and/or Materials. Moreover, such third party will be required to acknowledge, in writing, any Funders' funding, where appropriate, with respect to such Gr-ADI Inventions and/or Materials and agree to adhere to the Global Access Objectives with respect to its use of the Gr-ADI Inventions and/or Material and any improvement, modification or invention resulting from their use.

## **5. CLARIFICATION ON RIGHTS OF Gr-ADI MEMBERS TO USE DATA, MATERIALS OR INVENTIONS**

For the purposes of clarity, nothing in this Agreement provides any rights in or licenses in favor of a Gr-ADI Member to use Data, Materials or Inventions owned by another Gr-ADI Member except to the extent expressly provided for in this Agreement and for the purpose of carrying out Gr-ADI Projects.

## **6. UNIQUENESS OF IDENTIFIERS**

For bookkeeping purposes in order to ensure that Data and Materials generated or provided may be associated with the Gr-ADI Member and investigator, all Gr-ADI Members will comply with an identification naming convention that will be used across the Gr-ADI which will be established by the Funders. Unique identifiers will be used to identify (consistent with applicable privacy laws and regulations) all Gr-ADI Members, investigators within the Gr-ADI Members, Material, documents, and Data, as well as transfers of Materials, documents and Data between Gr-ADI Members.

## ANNEX D

### MASTER Gr-ADI CONFIDENTIAL DISCLOSURE AGREEMENT

WHEREAS, the Gr-ADI Members anticipate that any exchange of information and data (including, without limitation, information concerning Materials) between Gr-ADI Members will be in accordance with the terms of this Master CDA.

WHEREAS, each Gr-ADI Member is interested in examining and evaluating other Gr-ADI Member's Confidential Information solely for the purpose of carrying out research activities within its own Gr-ADI Project (the "**Purpose**").

Now, therefore, the Gr-ADI Members agree, by virtue of their agreement to the Cooperation and Sharing Agreement, to the following terms and conditions with respect to the transfer of Confidential Information between Gr-ADI Members:

#### DEFINITIONS

**Confidential Information** means, subject to Section 5, all information provided at any Gr-ADI-Related Communication with respect to any aspect of a Gr-ADI Project, including Data, Compound Structure Data and Gr-ADI Inventions. Confidential Information in a documentary or written form should be marked as confidential to be considered Confidential Information. A written record is not required, however, for information to be considered as Confidential Information where the information was provided orally and indicated as being confidential.

**Gr-ADI-Related Communication** means any meeting, discussion or activity (whether in person, electronically, by phone or otherwise) among or on behalf of multiple Gr-ADI Members.

Capitalized terms not otherwise defined in this Master CDA shall have the definitions as provided to them in Annex B to the Gr-ADI Cooperation & Sharing Agreement.

#### TERMS AND CONDITIONS OF THIS AGREEMENT

1. The terms and conditions of this Master CDA include the provisions set forth below, as well as the provisions of the Guiding Principles which are hereby incorporated by reference and made a part of this Master CDA. In the event that there are any conflicts between the provisions set forth below and those set forth in the Guiding Principles, the provisions of the Guiding Principles shall control.
2. Each Gr-ADI Member (as a **Disclosing Party**) may, at its own discretion, disclose certain Confidential Information owned or rightfully possessed by it to other Gr-ADI Members (each as the **Receiving Party**).
3. The Gr-ADI Members shall ensure that all participants under their control in a Gr-ADI-Related Communication will have executed an agreement prior to their receipt of Confidential Information obligating them to refrain from disclosure or use of Confidential Information in any manner inconsistent with this Master CDA.
4. Each Gr-ADI Member, as a Receiving Party, agrees that it will:

- (a) use the Confidential Information received from a Disclosing Party solely for the Purpose;

(b) treat the Confidential Information with reasonable care to avoid disclosure of the Confidential Information to any third party, person, firm or corporation other than as expressly stated herein; and

(c) be liable for use of the Disclosing Party's Confidential Information outside the scope of the Purpose as well as for any unauthorized disclosure directly resulting from its failure to exercise such reasonable care.

5. Notwithstanding anything to the contrary in this Master CDA, the Receiving Party shall have no obligation with respect to the Confidential Information received from a Disclosing Party to the extent such information is:

(a) already known by the Receiving Party or its Affiliates at the time of disclosure, as can be demonstrated by competent proof;

(b) publicly known, or subsequently becomes publicly known, without the wrongful act or breach of this Master CDA by the Receiving Party;

(c) rightfully received by the Receiving Party or its Affiliates from a third party having the lawful right to make such a disclosure, where said disclosure is rightfully made without any obligation of confidence to the Disclosing Party;

(d) approved for release or disclosure by written authorization of the Disclosing Party;

(e) independently developed by or for the employees or agents of the Receiving Party or its Affiliates without the use or knowledge of the Confidential Information provided by the Disclosing Party as can be demonstrated by competent proof; or

(f) required to be disclosed pursuant to any competent judicial or government request, requirement or order, provided that the Receiving Party so disclosing takes reasonable steps to provide the Disclosing Party with sufficient prior notice in order to allow the Disclosing Party to contest such request, requirement or order, and provided further that such Confidential Information is disclosed only subject to reasonably available restrictions on further disclosure and use, and otherwise remains subject to the obligations of confidentiality and restricted use set forth in this Master CDA.

6. Each Receiving Party shall be entitled to disclose the Disclosing Party's Confidential Information to its employees and the employees of its Affiliates, as well as its agents and consultants who are bound by confidentiality and restricted use obligations no less strict than those set out herein. However, each Receiving Party shall only disclose the Disclosing Party's Confidential Information to those of its employees, agents, consultants and Affiliates who reasonably need to know such Confidential Information in order to further the Purpose and/or to make decisions or render advice in connection with the Purpose and who shall be informed of the existence of this Master CDA and shall agree in writing or via employment policy to be bound by the terms hereof or be otherwise bound by law not to disclose such Confidential Information. Each Receiving Party shall be responsible for

ensuring that its employees, agents and consultants, and those of its of its Affiliates who receive Confidential Information comply with the terms of this Master CDA.

7. Notwithstanding the provisions of Paragraphs 4 and 6 above, the transfer, disclosure, use, dissemination, and publication of specific types of Data (as that term is defined in the Gr-ADI Cooperation & Sharing Agreement and as applied in the Guiding Principles) will be governed by the provisions of the Guiding Principles.

8. Subject to exemptions and limitations elsewhere in this Master CDA, the obligations of Paragraph 4 shall remain in effect for each subject disclosure of Confidential Information for a period of five (5) years from date of the termination of the appertaining Gr-ADI Projects for which Confidential Information has been transferred or Five (5) years from termination of the Agreement, whichever is shorter.

9. Unless otherwise expressly agreed upon by the Disclosing Party and the Receiving Party, no rights additional to those enumerated in Paragraph 4(a) in the Confidential Information are provided to any Gr-ADI Member under any patent applications, patents, or other proprietary rights of the Disclosing Party. Except as allowed under Paragraph 5 above, no Gr-ADI Member shall be entitled to use the Confidential Information provided by the Disclosing Party for commercial purposes without separate written agreement to that effect. Nothing contained in this Master CDA shall be construed as an obligation to enter into any further agreement relating to any of the Confidential Information or as a grant of a license to the Receiving Party to use the Disclosing Party's Confidential Information other than for the Purpose.

10. The Receiving Party agrees to discontinue its use of the Confidential Information and destroy or return to the Disclosing Party all written Confidential Information (whether received in written form or reduced to a written form following receipt) upon request by the Disclosing Party; provided, however, one (1) copy of such Confidential Information may be retained by the Receiving Party to preserve an archival record of the same to monitor ongoing legal and/or regulatory obligations.

11. Any dispute or controversy arising in connection with this Master CDA shall first be referred to the respective senior management of the Disclosing and Receiving Parties, or their successors, for attempted resolution in good faith negotiations within thirty (30) days of notice of such dispute. If such senior management are not able to resolve the dispute within the thirty (30)-day period, or any agreed upon extensions, the Disclosing and Receiving Parties shall be free to resolve the dispute through any dispute resolution mechanism they may individually or collectively choose. The Parties agree that should this Master CDA be breached, the non-breaching party shall be entitled to seek, and a court of competent jurisdiction may grant, specific performance and injunctive or other equitable relief as a remedy for any breach of this Master CDA. Such remedy shall be in addition to all other remedies, including money damages, available to a non-breaching party at law or in equity.

12. Upon request of either the Disclosing Party or the Receiving Party, the transfer of Confidential Information may be documented through a Confidential Information Transfer Record Form (in the form as contained in **Attachment A**) to be completed by the Disclosing and the Receiving Party. For purposes of clarification, the use of a Confidential Information Transfer Record Form is not required in order to categorize any information or data as confidential.

13. Except as certain provisions may survive as set forth in Paragraph 14 below, this Master CDA will terminate (including but not limited to termination as regards Confidential Information transferred

under any and all subject Confidential Information Transfer Record Forms not previously terminated) upon the termination of the Gr-ADI Project of either the Disclosing Party or the Receiving Party or if the Receiving Party is in breach of any of the conditions of this Master CDA.

14. The Definitions and Paragraphs 1, 4, 5, 7-11, 13, and 18 herein shall survive any termination or expiration of this Master CDA.

15. If any provision of this Master CDA is found to be unenforceable, such provision will be limited or deleted to the minimum extent necessary so that the remaining terms remain in full force and effect.

16. No waiver of any term, provision or condition of this Master CDA, whether by conduct or otherwise, in any one or more instances, shall be deemed to be or construed as a further or continuing waiver of the same term, provision or condition, or of any other term, provision or condition of this Master CDA.

17. The Disclosing Party understands and acknowledges, that prior to the Effective Date of this Master CDA, the Receiving Party and/or its Affiliates may have performed or engaged in, or otherwise arranged for the conducting of research, development and commercialization activities relating to the subject matter of the Disclosing Party's Confidential Information. Accordingly, the Disclosing Party acknowledges and agrees that nothing in this Master CDA will be construed by implication or otherwise as preventing the Receiving Party and/or its Affiliates, during the term of this Master CDA or thereafter, from (i) either internally or with a third party, engaging in research, development and commercialization activities relating to the subject matter of the Disclosing Party's Confidential Information, and (ii) evaluating such programs and capabilities of third parties relating to the subject matter of the Disclosing Party's Confidential Information, provided, that in each case of (i) and (ii), the Receiving Party does not use the Disclosing Party's Confidential Information in connection therewith.

**ATTACHMENT A  
CONFIDENTIAL INFORMATION TRANSFER RECORD FORM**

**DISCLOSING PARTY (*Institution/Company name*):**

**DISCLOSING PARTY SCIENTIST:**

**RECEIVING PARTY (*Institution/Company name*):**

**RECEIVING PARTY SCIENTIST:**

**Description of the Confidential Information: *Exhibit I (attached)***

The ORIGINAL CONFIDENTIAL INFORMATION described in Exhibit I (attached) is / are supplied by the DISCLOSING PARTY to the RECEIVING PARTY subject to the terms and conditions of the MASTER CDA.

The DISCLOSING PARTY hereby gives its authorization for the RECEIVING PARTY to further transfer the Confidential Information to other Gr-ADI Members in accordance with the terms of the Master CDA. The DISCLOSING PARTY gives such authorization by initialing here: \_\_\_\_\_

Description of the intended and authorized use of the Confidential Information: \_\_\_\_\_

\_\_\_\_\_  
(Use additional pages if required)

The following are the terms and conditions of the allocation of ownership/licensing of Confidential Information and Gr-ADI Inventions and other inventions that arise from use of the Confidential Information. This Disclosing and Receiving Party recognize that these terms and conditions must take into account and be consistent with the objectives and intentions of the Guiding Principles and the Global Access Objectives:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_  
(Use additional pages if required)

[*Optional clause*] Any dispute or controversy arising in connection with the transfer of Confidential Information documented herewith which is not resolved by the designated officers of this Disclosing Party and the Receiving Party in accordance with the Master CDA shall be finally settled in accordance with the following terms:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**DISCLOSING PARTY**

**RECEIVING PARTY**

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

*Read and Understood:*

**DISCLOSING PARTY SCIENTIST**

**RECEIVING PARTY SCIENTIST**

By: \_\_\_\_\_  
Name: \_\_\_\_\_

By: \_\_\_\_\_  
Name: \_\_\_\_\_



## **EXHIBIT I**

### **ORIGINAL CONFIDENTIAL INFORMATION**

List the type of Confidential Information to be transferred and, if applicable, identify the software (and version) used to compile or organize the information.

## ANNEX E

### MASTER Gr-ADI MATERIAL TRANSFER AGREEMENT

WHEREAS, consistent with the Gr-ADI Cooperation & Sharing Agreement, the terms of this Material Transfer Agreement (**Master MTA**) shall govern the transfer of Materials from and between the Gr-ADI Members in connection with activities carried out under a Gr-ADI Project. The Gr-ADI Members recognize that **Attachment A** contains additional standard MTA provisions for use with this Master MTA for use when transferring Material that is created or used within activities of the Gr-ADI but is to be transferred to organizations that are not Gr-ADI Members.

Now, therefore, the Gr-ADI Members agree to the following terms and conditions with respect to the transfer of Materials between Gr-ADI Members.

**DEFINITIONS:** All capitalized terms not otherwise defined in this Master MTA shall have the definitions provided in Annex B to the Gr-ADI Cooperation & Sharing Agreement.

**Provider** means the entity that is providing the Materials and / or having the Materials provided by another entity on its behalf, including the principal investigator and / or co-principal investigator or his/her designee employed by such entity who will be physically supplying the Materials.

**Recipient** means the entity that is receiving the Materials, including the principal investigator or, where applicable, co-principal investigator or his/her designee employed by such entity who will be physically receiving the Materials.

#### **TERMS AND CONDITIONS OF THIS AGREEMENT:**

1. The terms and conditions of this Master MTA include the provisions of the Guiding Principles, which are hereby incorporated by reference and made a part of this Master MTA. In the event that there are any conflicts between the provisions set forth below and those set forth in the Guiding Principles, the provisions of the Guiding Principles shall control. Moreover, Materials and information provided to the Recipient are considered to be the Confidential Information of the Provider under the terms of the Master CDA.
2. Transfer of any Materials by Gr-ADI Members under this Master MTA shall be documented through the completion of the Material Transfer Record Forms (in the form as contained in **Attachment B**), a copy of which will be provided by the Provider to the Funders for each Material transfer.
3. The Recipient agrees that Materials (a) will not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects unless such use is expressly approved by the Provider in writing; (b) will not be used for commercial purposes; (c) will only be used by individuals who are legally obligated, in the manner and to the extent required in the applicable Material Transfer Record Forms, to assign their respective right in any and all Gr-ADI Inventions (and any patent rights or other rights arising therefrom); and (d) will not be given to or made available to other Gr-ADI Members or third parties.

4. The Provider may Publish on Data generated by Recipient when using Materials it received from Provider. Such Publication shall be accompanied by the appropriate attributions (co-authorship or acknowledgement as appropriate) of the Recipient as having contributed to the generation of the Data. The Recipient may also publish on such Data, accompanied by the appropriate attribution (co-authorship or acknowledgement as appropriate) of the Provider. The Party desiring to publish on Data shall furnish the Provider or Recipient, as the case may be, with a copy of any proposed Publication for review and comment at least forty-five (45) days prior to submission for publication and shall reasonably consider any comments provided and requested amendments to the text to protect Confidential Information, in particular through its removal. However, nothing herein shall be interpreted to require the publishing Party to delete or alter the Data and conclusions of the study in any publication. If during the review period, the Provider notifies the publishing Party that it desires to establish a patent filing strategy, to accommodate filing patent applications on disclosed inventions, publishing Party will defer publication or other disclosure for a period, not to exceed an additional forty-five (45) days, sufficient to permit the Provider or its designee to have filed or to file any desired patent applications. At the end of the review period, the publishing Party will have the right to proceed with the publication. The Recipient agrees to promptly provide a report to the Provider of the results for research in which the Materials were utilized.

5. (a) It is understood and agreed that the attachments to this Master MTA, and the Gr-ADI Cooperation & Sharing Agreement, set forth certain other provisions regarding confidentiality, the sharing of Data, Gr-ADI Inventions, Publications, the scientific and charitable goals of the Gr-ADI Projects, and other related issues and appertaining activities under this Master MTA.

(b) The use and allocation of ownership or licensing, if any, of the Materials, research results, and Gr-ADI Inventions arising through the use of the Materials is addressed in the applicable Material Transfer Record Forms. Such ownership or licensing provisions shall survive termination of the Master MTA.

6. Any Materials transferred pursuant to this Master MTA are understood to be experimental in nature and may have hazardous properties. THE PROVIDER MAKES NO REPRESENTATIONS NOR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIALS WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER THIRD PARTY PROPRIETARY RIGHTS, OR THAT THE MATERIALS WILL NOT POSE A HEALTH OR SAFETY RISK.

7. The Materials are supplied without cost to Gr-ADI Members but, unless provided otherwise, the Recipient shall reimburse the Provider for any reasonable shipping and related costs that may be incurred when preparing and sending the Materials to the Recipient. The Recipient and recipient scientist shall use the Materials in accordance with good laboratory practice and the highest standards of skill and care and shall ensure compliance with any applicable laws and regulations governing the transportation, keeping or use of the Materials.

8. Except to the extent prohibited by applicable law, the Recipient assumes all liability for claims for damages that may arise from its use, storage, and/or disposal of the Materials for any activities related to the Material. The Provider will not be liable to the Recipient for any loss, claim, or demand

made by the Recipient, or made against the Recipient by any other party, due to or arising from the use, storage, and/or disposal of the Materials by the Recipient, except to the extent permitted by applicable law when such loss, claim, or demand is caused by the gross negligence and/or willful misconduct of the Provider. All Materials will be shipped EXW<sup>3</sup> Provider's place of business for activities carried out pursuant to this Agreement (unless Provider and Recipient mutually agree to a different Incoterm shipping classification).

9. The Provider certifies that, if applicable to the Material being supplied under this Master MTA, it has obtained all informed consent(s) and / or other necessary approval(s) and / or authorization(s) in the collection of the Materials necessary to provide the Materials for use in accordance with the respective Material Transfer Record Form. The Recipient agrees to handle, store, and use the Materials in a safe manner and in compliance with all applicable statutes and regulations, including applicable governmental regulations and guidelines as well as the requirements of national drug regulatory authorities and other relevant regulatory agencies. The Recipient certifies that it has obtained any Institutional Review Board and / or Ethics Committee and / or other approvals that may be required for the use of Materials received under this Master MTA as outlined in the respective Material Transfer Record Form.

10. This Master MTA will terminate as regards Materials transferred under a subject Material Transfer Record Form on the earliest of the following dates: (a) on completion of the Recipient's use of the Materials for the Gr-ADI Projects; or (b) on termination of the appertaining Gr-ADI Projects for which Materials were transferred. Upon such termination Recipient will immediately discontinue its use of the Materials and will, upon direction of the Provider, return or destroy any remaining Materials. Termination of the Provider's Gr-ADI Project shall not affect the Provider's rights hereunder.

11. Except as certain provisions may survive as set forth in Paragraph 12 below, this Master MTA will terminate in its entirety (including but not limited to termination as regards Materials transferred under any and all subject Material Transfer Record Forms not previously terminated) upon the termination of the Gr-ADI Project of either the Provider or the Recipient or if the Recipient is in breach of any of the conditions of this Master MTA.

12. The Definitions and Sections 1 and 4-15 herein, the Gr-ADI Cooperation & Sharing Agreement, and the rights of any Provider set forth herein shall survive any termination or expiration of this Master MTA, including but not limited to subject termination as regards Materials transferred under a subject Material Transfer Record Form.

13. Any dispute or controversy arising in connection with this Master MTA shall first be referred to the Parties' senior management, on behalf of the Recipient and the Provider, or their successors, for attempted resolution in good faith negotiations within thirty (30) days of notice of such dispute. If such senior management are not able to resolve the dispute within the thirty (30)-day period, or any agreed upon extensions, the Disclosing Party and the Receiving Party shall be free to resolve the dispute through any dispute resolution mechanism they may individually or collectively choose.

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<sup>3</sup> EXW is an Incoterm abbreviation for "EX Works." Ex works means that the Provider delivers when he places the goods at the disposal of the Recipient at the Provider's premises or another named place (i.e. works, factory, warehouse, etc.) not cleared for export and not loaded on any collecting vehicle. This term thus represents the minimum obligation for the Provider, and the Recipient has to bear all costs and risks involved in taking the goods from the Provider's premises.

14. If any provision of the Agreement is found to be unenforceable, such provision will be limited or deleted to the minimum extent necessary so that the remaining terms remain in full force and effect.

15. No waiver of any term, provision or condition of this Master MTA, whether by conduct or otherwise, in any one or more instances, shall be deemed to be or construed as a further or continuing waiver of the same term, provision or condition, or of any other term, provision or condition of this Master MTA.

## ATTACHMENT A

**[This attachment includes additional provisions that must be included in a Material Transfer Agreement when transferring Materials that are created within activities of the Gr-ADI to Recipients that are not Gr-ADI Members.]**

1. The Recipient acknowledges that it has read, understands and agrees to be bound by the terms of the Gr-ADI Master MTA.
2. The Recipient will adhere to the following Global Access Objectives: (i) the broad and prompt dissemination of research information generated through use of the Materials to the scientific community and (ii) that any entity commercialising a new antibiotic developed from a Gr-ADI-funded lead compound considers the most appropriate ways in which to provide responsible stewardship of, and equitable access to, the new product once it reaches the market to people most in need within low- and middle-income countries..
3. The Provider will require any person or entity to whom or which it provides the Materials (if allowed to do so) and any improvements, modifications or inventions that have arisen through the use of the Materials to include the Global Access Objectives stated above in paragraph 2 in connection with agreements through which it provides the Materials or permission or licenses to use such improvements, modifications or inventions.

## ATTACHMENT B MATERIAL TRANSFER RECORD FORM

**PROVIDER** (*Institution/Company name*):

**PROVIDER Contact:**

**RECIPIENT** (*Institution/Company name*):

**RECIPIENT Contact:**

**Description of the MATERIAL:** *Exhibit I (attached)*

The ORIGINAL MATERIAL(S) described in Exhibit I (attached) is / are supplied by the PROVIDER to the RECIPIENT subject to the terms and conditions of the Gr-ADI Master MTA.

Transfers by the Recipient to non-Gr-ADI Members are specifically prohibited. Further transfers of MATERIAL by the RECIPIENT to other Gr-ADI Members may be made only by PROVIDER.

Description of the intended and authorized use of the MATERIALS: \_\_\_\_\_

\_\_\_\_\_  
(Use additional pages if required)

Describe any special handling or storage instructions for the MATERIALS: \_\_\_\_\_

\_\_\_\_\_  
(Use additional pages if required)

The following are the terms and conditions of the use, transfer, allocation of ownership/licensing of Materials and Gr-ADI Inventions, research results, and other inventions that arise from use of the Materials. This Provider and the Recipient recognize that these terms and conditions must take into account and be consistent with the objectives and intentions of the Guiding Principles and the Global Access Objectives:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
(Use additional pages if required)

By signing, the RECIPIENT accepts all terms and conditions expressly stated in this Material Transfer Record and/or Exhibit I.

**PROVIDER**

**RECIPIENT**

By: \_\_\_\_\_  
 Name: \_\_\_\_\_  
 Title: \_\_\_\_\_  
 Date: \_\_\_\_\_

By: \_\_\_\_\_  
 Name: \_\_\_\_\_  
 Title: \_\_\_\_\_  
 Date: \_\_\_\_\_

Duplicate originals of this form shall be fully completed and executed with: (i) the Recipient being notified by the Provider of the upcoming transfer via a copy of the completed subject Material Transfer Record Form (supplied electronically via facsimile transmission, attachment as an image file to e-mail, or the like) within seventy-two (72) hours of the Provider’s completion and execution of this Material Transfer Record Form and (ii) a copy being supplied electronically (via facsimile transmission, attachment to e-mail as an image file, or the like) to \_\_\_\_\_and / or facsimile number \_\_\_\_\_or to such other e-mail address and/ or facsimile number as may be provided by the Foundation in the future) by the Provider within seventy-two (72) hours of its completion and execution of this Material Transfer Record Form.



## **EXHIBIT I**

### **ORIGINAL MATERIAL(S)**

Describe the Material being transferred under this Material Transfer Record as well as the unique barcode identifier or other unique identifier.