AZIENDA OSPEDALIERO UNIVERSITARIA MEYER

Delibera del Direttore Generale n. 624 del 29-11-2023

Proposta n. 1124 del 2023

Oggetto: ACCORDO DI RISERVATEZZA CON INOZYME PHARMA, INC. PRELIMINARE A POSSIBILE FUTURO STUDIO CLINICO – APPROVAZIONE SCHEMA DI ACCORDO

Dirigente: MCGREEVY KATHLEEN

Struttura Dirigente: RESP. MEYER CHILDREN'S RESEARCH INSTITUTE

AZIENDA OSPEDALIERA UNIVERSITARIA MEYER I.R.C.C.S.
Istituto di Ricovero e Cura a Carattere Scientifico
Viale Pieraccini, 24 - 50139 FIRENZE
C.F. P.Iva 02175680483

DELIBERAZIONE DEL DIRETTORE GENERALE

Oggetto	Sperimentazione clinica
Contenuto	ACCORDO DI RISERVATEZZA CON INOZYME PHARMA, INC. PRELIMINARE A POSSIBILE FUTURO STUDIO CLINICO – APPROVAZIONE SCHEMA DI ACCORDO

Area Tecnico Amm.va	AREA TECNICO AMMINISTRATIVA
Coord. Area Tecnico Amm.va	BINI CARLA
Struttura	MEYER CHILDREN'S RESEARCH INSTITUTE
Direttore della Struttura	MCGREEVY KATHLEEN
Responsabile del procedimento	FABBIANO ALESSIO
Immediatamente Esecutiva	SI

Spesa prevista	Conto Economico	Codice Conto	Anno Bilancio

Estremi relativi ai principali documenti contenuti nel fascicolo		
Allegato	**N° di pag.**	**Oggetto**
1	7	Confidentiality Agreement
2	7	Confidentiality Agreement

"documento firmato digitalmente"

IL DIRETTORE GENERALE
Dr. Paolo Morello Marchese
(D.P.G.R.T. n. 149 del 28 agosto 2023)

Richiamati:

- il Decreto Legislativo n. 502 del 30.12.1992 e successive modifiche ed integrazioni, recante "*Riordino della disciplina in materia sanitaria, a norma dell'art.1 della legge 23 ottobre 1992, n. 421*";
- il Decreto Legge n. 75 del 22 .06.2023, così come modificato dalla Legge n. 112 del 10.08.2023, recante "*Disposizioni urgenti in materia di organizzazione delle pubbliche amministrazioni, di agricoltura, di sport, di lavoro e per l'organizzazione del Giubileo della Chiesa cattolica per l'anno 2025"* ed in particolare l'art. 8-bis, contenente "*Disposizioni in materia di dirigenza sanitaria, amministrativa, professionale e tecnica del Servizio sanitario nazionale*";
- la Legge Regionale Toscana n. 40 del 24.02.2005 e successive modifiche ed integrazioni, di "*Disciplina del Servizio Sanitario Regionale*";
- la Legge Regionale Toscana n. 12 del 16.03.2023 e successive modifiche ed integrazioni "*Disposizioni in materia di istituti di ricovero e cura a carattere scientifico pubblici. Modifiche alla l.r. 40/2005*" con la quale si è proceduto alla disciplina degli istituti di ricovero e cura a carattere scientifico di diritto pubblico ed in particolare l'art. 13 con il quale sono state dettate le "*Disposizioni transitorie per il passaggio da Azienda Ospedaliero Universitaria Meyer ad Azienda Ospedaliera Universitaria Meyer IRCCS…*";

Visto il Decreto del Presidente della Giunta Regionale n. 149 del 28.08.2023 con il quale il Dr. Paolo Morello Marchese è stato nominato Direttore Generale dell'Azienda Ospedaliera Universitaria Meyer IRCCS;

Dato atto che**:**

- con deliberazione del Direttore Generale n. 54 del 01.02.2021 è stato approvato il nuovo Atto Aziendale dell'A.O.U. Meyer, ai sensi dell'art. 6 del Protocollo d'intesa del 22.04.2002 fra Regione Toscana e Università degli Studi di Firenze, Siena e Pisa, con decorrenza dal 01.02.2021;
- con deliberazione del Direttore Generale n. 55 del 01.02.2021 sono stati assunti i primi provvedimenti attuativi in relazione alla conferma/riassetto delle strutture complesse e semplici dotate di autonomia ed al conferimento dei relativi incarichi di direzione;
- con deliberazione del Direttore Generale n. 56 del 01.02.2021 sono state assunte determinazioni attuative del nuovo Atto aziendale in relazione alla conferma/riassetto delle strutture Dipartimentali e/o a valenza dipartimentale, delle Aree Funzionali Omogenee, dell'Area Servizi dell'Ospedale, dell'Area dei Diritti del Bambino, dell'Area Tecnico Amministrativa ed al conferimento di relativi incarichi di direzione;
- con successiva deliberazione del Direttore Generale n. 92 del 15.02.2021 si è provveduto ad assumere ulteriori disposizioni attuative relative all'organizzazione dell'A.O.U. Meyer in ordine alle Strutture semplici Intrasoc, Unità Professionali, Uffici e Incarichi professionali;
- con deliberazione del Direttore Generale n. 443 del 23.09.2022 l'A.O.U. Meyer ha disposto la presa d'atto del Decreto del Ministero della Salute del 02.08.2022, pubblicato nella Gazzetta Ufficiale n. 200 del 27.08.2022, con cui l'Azienda Ospedaliero Universitaria Meyer è

stata riconosciuta Istituto di Ricovero e Cura a Carattere Scientifico (I.R.C.C.S.), per la disciplina di pediatria;

Su proposta del Responsabile del Meyer Children's Research Institute, Dr.ssa Kathleen McGreevy, la quale, con riferimento alla presente procedura, ne attesta la regolarità amministrativa e la legittimità dell'atto;

Ricordato che questa Azienda, tra le proprie finalità istituzionali, promuove la ricerca scientifica con lo scopo di raggiungere risultati di eccellenza nella cura in campo pediatrico e che taluni progetti di ricerca, prima del loro avvio, necessitano di una fase preliminare atta ad esplorarne la fattibilità presso le proprie strutture;

Considerato che la società farmaceutica Inozyme Pharma, Inc. ha manifestato il proprio interesse a condurre una sperimentazione clinica nel campo delle malattie cardiologiche che vede coinvolti la Dr.ssa Silvia Favilli e il Prof. Iacopo Olivotto;

Evidenziato che è nell'interesse dell'AOU Meyer IRCCS esplorare la possibilità di condurre la su citata sperimentazione e garantire la valorizzazione della ricerca in pediatria;

Stabilito, pertanto, che è nelle intenzioni di questa Azienda scambiare con la suddetta società, attraverso apposito Accordo di riservatezza, talune informazioni riservate necessarie per esaminare l'opportunità e la realizzabilità di uno studio clinico;

Verificato che dall'Accordo di cui sopra non derivano oneri economici a carico dell'AOU Meyer IRCCS;

Ritenuto pertanto di stipulare l'Accordo di riservatezza con Inozyme Pharma, Inc. in due esemplari ciascuno per i due sperimentatori sopra citati, per la disciplina delle condizioni normative ed operative per la tutela delle informazioni confidenziali scambiate tra le parti dell'Accordo, secondo gli schemi che, allegati N. 1 e N. 2 al presente atto, ne formano parte integrante e sostanziale;

Rilevata l'opportunità di dichiarare il presente atto immediatamente eseguibile per consentire che le informazioni confidenziali siano oggetto di reciproco scambio in tempi congrui con le esigenze di confronto, nel breve periodo, sulla fattibilità di uno studio clinico da eseguire nelle strutture dell'AOU Meyer IRCSS;

Considerato che il Responsabile del Procedimento, individuato ai sensi della Legge n. 241/1990 nella persona del Dr. Alessio Fabbiano, sottoscrivendo l'atto attesta che lo stesso, a seguito dell'istruttoria effettuata, nella forma e nella sostanza è legittimo;

Acquisito il parere del Dr.ssa Carla Bini, Coordinatore dell'Area Tecnico Amministrativa, espresso mediante sottoscrizione del presente atto;

Vista la sottoscrizione del Direttore Sanitario e del Direttore Amministrativo, per quanto di competenza, ai sensi dell'art. 3 del Decreto Legislativo n. 229/99;

DELIBERA

Per quanto esposto in narrativa che espressamente si richiama,

1) Di approvare lo schema di Accordo di riservatezza da stipulare con Inozyme Pharma, Inc. in due esemplari ciascuno per i due sperimentatori citati in premessa, che, allegati N. 1 e N. 2 al presente atto, ne formano parte integrante e sostanziale.
2) Di dare atto che dall'Accordo di cui sopra non derivano oneri economici a carico dell'AOU Meyer IRCCS.
3) Di dichiarare il presente atto immediatamente eseguibile ai sensi dell'art. 42, comma 4 della L.R. T. n. 40/2005 in considerazione della necessità di procedere in tempi brevi alla sottoscrizione del su citato Accordo e consentire così nell'immediato la discussione reciproca tra le parti relativamente alla fattibilità di uno studio clinico da eseguirsi presso l'AOU Meyer IRCCS.
4) Di trasmettere il presente atto al Collegio Sindacale ai sensi dell'art. 42, comma 2, della L.R.T. n. 40/2005 contemporaneamente all'inoltro all'albo di pubblicità degli atti di questa A.O.U. Meyer I.R.C.C.S.

IL DIRETTORE GENERALE
(Dr. Paolo Morello Marchese)

IL DIRETTORE SANITARIO
(Dr. Emanuele Gori)

IL DIRETTORE AMMINISTRATIVO
(Dr. Lorenzo Pescini)

CONFIDENTIALITY AGREEMENT

Azienda Ospedaliera Universitaria Meyer - Istituto di Ricovero e Cura a Carattere Scientifico with registered office at **Viale G. Pieraccini 24 50139 Firenze** represented by its Legal Representative and CEO Dr Paolo Morello Marchese ("**Recipient**") desires to engage in discussions and review Confidential Information (as defined below) relating generally to a study sponsored by **Inozyme Pharma, Inc.** ("**Sponsor**"), with its principal place of business at 321 Summer Street, Suite 400, Boston, MA 02210 USA, having the protocol: **INZ701 Program**, as may be amended from time to time (the "**Study**"). **Worldwide Clinical Trials Limited**, organized according to laws of England and Wales with its principal place of business at Fourth Floor, East West, Tollhouse Hill, Nottingham, NG1 5FS, UK together with its Affiliates (collectively "**Discloser**") desires to protect such Confidential Information from unauthorized use and disclosure and will only disclose such Confidential Information to the Recipient if Recipient agrees to the terms and conditions of this Agreement (this "**Agreement**"). Recipient and Discloser may hereinafter be individually referred to as a "**Party**" and collectively as the "**Parties**".

This Agreement is effective as of the date of the Recipient's signature below (the "**Effective Date**"). For purposes of this Agreement, "**Affiliates**" means any entity that controls, is under common control, or is controlled by a Party.

The Discloser will disclose Confidential Information to the Recipient's Principal Investigator, Dr Silvia Favilli (the "**Principal Investigator**"), who signs this Agreement for acceptance of the terms and conditions herein.

For good and valuable consideration including the contemplated contractual relationship with Discloser, the sufficiency of which is hereby acknowledged, Recipient herby agrees as follows:

1. Definition of Confidential Information. "**Confidential Information**" shall mean (i) all confidential and proprietary information in whatever form, used by, or belonging to, or relating to the Discloser or Sponsor or their Affiliates, officers, directors, employees, subcontractors, consultants, professional advisors or agents ("**Representatives**"), which is not generally known to the public or to the industry in which Discloser or any of the foregoing is or may become engaged in; (ii) all other information which Discloser advises the Recipient in writing should be treated as confidential, (iii) all copies and duplications of any such information, as well as any documents prepared by Recipient, which contain, incorporate by reference or reflect any Confidential Information of Discloser or Sponsor or their Representatives. Recipient acknowledges that no Recipient personal data governed by the European Union's ("**EU**") General Data Protection Regulation ("**GDPR**") or UK GDPR will be disclosed to Discloser or Sponsor in connection with this Agreement, unless necessary to accomplish the purpose of this Agreement. In cases of any such disclosure, Recipient represents that it has taken all necessary steps to assure that any such disclosure is made in compliance with the GDPR. Recipient acknowledges receipt of the Privacy Notice for site personnel ("**Privacy Notice**") attached to the Agreement as Appendix 1 and shall distribute the Privacy Notice to any of its Representatives or any other GDPR covered person disclosing personal data to Sponsor or Discloser under this Agreement

2. Nondisclosure and Non-Use Obligations. Recipient and Principal Investigator shall not disclose the Confidential Information to any third parties without the written consent of Discloser other than its Representatives, shall use such Confidential Information only to evaluate whether Recipient and Principal Investigator are interested in participating in the Study as a clinical study site or investigator, as applicable (the "**Purpose**"), shall not reverse engineer such Confidential Information and shall implement practices and procedures necessary to prevent such disclosure, which steps shall include at least those taken by Recipient to protect its own confidential information of like kind, but in no case less than a reasonable degree of care provided, however, that Recipient may disclose Confidential Information to Recipient's Affiliates and its Representatives (including any study team member under Recipient's supervision, study site personnel, or local ethics committee) who have a need to know, but only to the extent reasonably necessary to carry out the Purpose. Recipient (i) will

inform Representatives that such Confidential Information is confidential and is not to be disclosed to third parties, (ii) will ensure that Representatives who actually receive Confidential Information will be subject to nondisclosure and nonuse obligations substantially similar to those in this Agreement, and (iii) will be responsible for any noncompliance by Representatives.

3. Exclusions from Nondisclosure and Nonuse Obligations. The obligations of nondisclosure and nonuse in Section 2 shall not apply to any information which Recipient can show (a) was already known by Recipient before receiving such information from Discloser, (b) is or becomes known to the public or generally available to the public through no fault of Recipient, (c) is rightfully furnished to Recipient from a third party who to Recipient's knowledge is not under an obligation of nondisclosure or nonuse, (d) is independently developed by or for Recipient without use of Confidential Information, or (e) is approved for disclosure by Discloser. In the event Recipient is required by a valid order of a court or other governmental body or regulatory authority Recipient will provide Discloser with prompt notice (to the extent permitted to do so by applicable law) so that Discloser or Sponsor may seek a protective order or other appropriate remedy or waive compliance with the provisions of this Agreement.

4. Confidentiality. During the performance of this Agreement, the Discloser, Sponsor or their respective Representatives may gain access through site visits, investigator's meeting or other written or oral discussions to information relating to Recipient's business or research operations, policies, or procedures that Recipient identifies to Discloser, Sponsor and their respective Representatives as proprietary and confidential or that is reasonably apparent to Discloser, Sponsor or their respective Representatives to be so. Unless Receiving Party provides written consent, Discloser, Sponsor and their respective Representatives will not copy or remove such information, use such information for any purpose other than performance of this Agreement, or disclose such information to any third party except as required by applicable laws.

5. Ownership and Return of Confidential Information and Other Materials. All Confidential Information and any derivatives thereof shall remain the property of Discloser or Sponsor, and no license or other rights to such Confidential Information or derivatives is granted or implied hereby. No Confidential Information, including but not limited to employee contact information, shall be sold, assigned, licensed, or leased to third parties or commercially exploited by or on behalf of Recipient unless expressly authorized by Discloser in order to carry out the Purpose. Recipient shall return to Discloser, upon written request and at Discloser sole cost, all Confidential Information, as well as all excerpts, summaries, and photocopies, electronic copies, or other reproductions or extracts thereof, and work sheets and the like pertaining thereto; provided however, Recipient may retain one (1) archival copy of Confidential Information for the sole purpose of determining its obligations hereunder and one (1) electronic copy as part of its standard electronic back-up system.

6. Term. This Agreement shall terminate one (1) year from the Effective Date; provided, however, that obligations with respect to the Confidential Information contained herein shall expire five (5) years after the date of disclosure thereof to Recipient, provided, further, however, the Recipient agree that after the five (5) year period referenced above, any Confidential Information that is subject to other protection under applicable law (including, without limitation, patent, trademark, and copyright law) will continue to be subject to the protection of such laws notwithstanding the expiration of such five (5) year period.

7. No Other Obligations or Warranty. Nothing in this Agreement shall constitute or imply any obligation of Discloser to disclose any Confidential Information, to sell or purchase any product or service of Recipient, to refrain from selling or purchasing any product or service from any third party, or any commitment with respect to the present or future marketing of any product or service. No rights or obligations other than those expressly recited herein are to be implied from this Agreement. All Confidential Information is provided "AS IS" and without any warranty, express, implied or otherwise, regarding such Confidential Information's accuracy, completeness, or performance. Recipient accepts all risk of use of, and reliance on, Confidential Information.

8. Injunctive Relief. Recipient and Principal Investigator acknowledge that damages may be an

inadequate remedy in the event of a breach or intended or threatened breach by Recipient or Principal Investigator of this Agreement and that any such breach may cause Discloser or Sponsor irreparable injury and damage; accordingly, Recipient and Principal Investigator acknowledge that Discloser or Sponsor may be entitled to seek (without waiving, to the extent not prohibited by applicable laws, any additional rights or remedies, including monetary damages, otherwise available to Discloser or Sponsor at law, or in equity, or by statute) preliminary and permanent injunctive relief in the event of a breach or intended or threatened breach by Recipient.

9. Governing Law. This Agreement shall be governed and enforced in accordance with the laws of Italy, without reference to conflict of laws principles. Any claim, controversy or dispute arising under or related to this Agreement will be governed by the laws of Italy.

10. Counterparts; Electronic Signatures. In the event that any signature is delivered by e-mail delivery of a ".pdf" format data file or other electronic means, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such signature page were an original thereof. The Recipient agrees that its electronic signature is the legal equivalent of any handwritten signature and the Recipient consents to signing this Agreement by electronic means.

11. Third Party Beneficiary. Recipient acknowledges and agrees that Sponsor is an express and intended third party beneficiary of the terms and conditions of this Agreement such that Sponsor shall be entitled to enforce any of the provisions of this Agreement and exercise the rights of Sponsor or Discloser set forth herein.

12. Miscellaneous. Any provision of this Agreement that is determined by a court of competent jurisdiction to be invalid, illegal or unenforceable in any jurisdiction shall, as to that jurisdiction only, be ineffective to the extent of such invalidity, illegality or unenforceability, without affecting in any way the remaining provisions hereof in such jurisdiction or rendering that or any other provision of this Agreement invalid, illegal or unenforceable in any other jurisdiction. Any waiver of, or promise not to enforce, any right under this Agreement shall not be enforceable unless evidenced by a writing signed by the Discloser.

This Agreement shall inure to the benefit of and be binding upon the parties hereto, and their successors and assigns.

In the event this Agreement is translated for informational purposes, the Recipient hereby acknowledges and agree that the English version is the original language. In the event of a conflict of any purported inconsistency, the English version will prevail and shall be the binding version.

This Agreement constitutes the final, entire, and exclusive agreement concerning the subject matter of this Agreement and supersedes all prior agreements, understandings, negotiations and discussions, written or oral, between Recipient and Discloser and/or Sponsor with respect thereto. Any modification, rescission or amendment of this Agreement shall not be effective unless made in writing executed by both parties.

Each party agrees that it shall not make a public announcement of this Agreement, or any other agreement between the Parties, the discussions or the potential relationship, without the prior written consent of the other parties, except as may be required by any applicable law, rule or regulation of any governmental body.

This Agreement shall not be construed as evidence of an intention to enter into business relations or transactions.

The parties are independent contractors. This Agreement does not create any employment relationship, partnership or principal-agent.

IN WITNESS WHEREOF, the Recipient hereto acknowledges that the representative named below has the authority to execute this Agreement on behalf of the Recipient to legally bind the Recipient to the terms of this Agreement.

[SIGNATURES ON NEXT PAGE]

Dr. Silvia Favilli

Signature :

Title: MD

Date:

Address for notice:
Viale G. Pieraccini 24
50139 Firenze

Institution: Azienda Ospedaliera Universitaria Meyer - Istituto di Ricovero e Cura a Carattere Scientifico

Signature:_____

Print Name: Dr Paolo Morello Marchese

Title: CEO

Date:

Address for notice:
Viale G. Pieraccini 24
50139 Firenze

Worldwide Clinical Trials, Ltd.

_____
(Signature)

Print Name: _____

Title: _____

Date:_____

Address for notice:
4th Floor, East West
Tollhouse Hill, Nottingham, NG1 5FS, UK

Appendix 1
Privacy Notice for Site Personnel

The purpose of this Privacy Notice is to provide information concerning the collection and use of your personal data in relation to the **INZ701 Program** (the "Study") sponsored by **Inozyme Pharma, Inc.** ("Sponsor") and managed by its contract research organization Worldwide Clinical Trials ("Worldwide").

What personal data is collected?

In connection with the Study, personal data may be collected from members of the Study team by or on behalf of Sponsor or Worldwide, in particular:

- Name and contact details;
- Where applicable, your professional identification number;
- Office / practice location, type, amenities, contact and communication preferences
- Curriculum vitae, including any licenses, certifications and professional affiliations;
- Information about debarment and any professional discipline measures from government sources or professional organizations
- Declaration of financial interests, if applicable;
- Affiliation with a Site Management Organization ("SMO")
- Financial information collected for payment
- Historical and current information regarding participation and performance in clinical studies;
- Training records; and
- Authentication information for entering data into the eCRF (electronic case report form).

How is your personal data used?
The Sponsor of the study, who is the controller of the personal data described above, either itself or through a service provider (including Worldwide), may collect, process, store and use the personal data for the following purposes:

a) In preparation of a feasibility questionnaire, a clinical trial contract, collection of documents and other start-up activities in preparation of your participation in the Study;
b) To comply with legal regulations related to the Study
c) To review and assess your historical and current involvement in clinical trials and to contact you regarding participation in the Study or future studies.

Worldwide is a processor acting on behalf of the Sponsor for the above-mentioned purposes but it will also act as independent controller of the Investigator's personal data described above for the following limited purpose, for which you will be asked to provide your consent:

a) To review and assess your historical and current involvement in clinical trials and inviting you regarding participation in future studies.

To whom could the personal data be disclosed?

In connection with the above purposes, the Sponsor and Worldwide may disclose the personal data to the following categories of recipients:
a) Competent authorities (including in the context of product registration);
b) Third parties who process the personal data on behalf of the Sponsor (including Worldwide)
c) Sponsor and its affiliates who are involved in the Study
d) Third parties who process the personal data on behalf of Worldwide or Sponsor
e) Worldwide affiliates

In the rare cases the personal data may be used in connection with investigations or legal proceedings, in which case the personal data may be disclosed to law enforcement agencies or other governmental authorities. It may also be shared with the Sponsor or Worldwide's advisors in such matters.

In connection with any of the above purposes, the personal data may be transmitted to countries outside the European Union or United Kingdom, as applicable, which are not regarded as providing an adequate level of protection for personal data, such as the United States. In those cases, your personal data shall only be transferred where appropriate safeguards are in place to protect your personal data, such as EU Standard Contractual Clauses.

The Sponsor or Worldwide or their affiliated companies have agreements in place with the service providers who may have access to the personal data as described above, under which they are bound to keep your information confidential and not to use it for any other reason other than for the purposes described in this notice. The Sponsor's and Worldwide advisors are bound by obligations of professional secrecy.

In the event Sponsor or Worldwide decides to reorganize or divest our business through sale, merger, or acquisition, Sponsor or Worldwide may share personal information about you with actual or prospective purchasers.

Legal Basis for Processing:

The legal basis for the collection and use of the personal data is:

- Legitimate Interests: where the processing of your personal data is necessary for the purposes of the legitimate interest of the Sponsor, linked with the Study;
- Legal obligation: the processing is necessary to comply with a legal obligation imposed on the Sponsor (or on a third party acting on behalf of the Sponsor), linked with the Study;
- Consent: To review and assess your historical and current involvement in clinical trials and inviting you regarding participation future studies.

Personal Data Retention:

We will only retain your personal information for as long as necessary to fulfil the purposes we collected it for in connection with the Study. To determine the appropriate retention period for personal data, we consider the amount, nature, and sensitivity of the personal data, the potential risk of harm from unauthorized use or disclosure of your personal data, the purposes for which we process your personal data and whether we can achieve those purposes through other means, and the applicable legal requirements.

Data Security:

Sponsor and Worldwide have put measures put in place to protect the security of your information in accordance with the respective company's information security policies and procedures.

Sponsor and Worldwide have put in place appropriate security measures to prevent your personal information from being accidentally lost, used or accessed in an unauthorized way, altered or disclosed. Sponsor and Worldwide have put in place procedures to deal with any suspected data security breach and will notify you and any applicable regulator of a suspected breach where we are legally required to do so.

What are the rights to personal data?

Members of the study team are entitled at any time to access their personal data and/or, to the extent legally permissible, to have such information deleted or corrected or to object to the processing of the personal data or to request the restriction of the processing of the personal data. Such rights can be exercised by notifying Sponsor or Worldwide data protection teams at the following:

Inozyme Pharma, Inc.
321 Summer Street, Suite 400
Boston, MA 02210 USA

via email to Sponsor's Data Protection Representative at Inozyme.DPO@MyData-Trust.info

- **Worldwide Clinical Trials**
  4th Floor, East West
  Tollhouse Hill, Nottingham, NG1 5FS, UK
  Attn: Data Privacy Representative

  or via email to Worldwide's Data Protection Officer at dpo@worldwide.com.

Should you object to the processing of your personal data, we may still be required to process your personal data to comply with applicable law, but we will explain to you at the time you object to what processing activities will continue for legal compliance purposes.

Members of the study team are entitled to lodge a complaint with their local supervisory authority, easily identified through the following link: https://edpb.europa.eu/about-edpb/board/members_en

CONFIDENTIALITY AGREEMENT

Azienda Ospedaliera Universitaria Meyer - Istituto di Ricovero e Cura a Carattere Scientifico with registered office at **Viale G. Pieraccini 24 50139 Firenze** represented by its Legal Representative and CEO Dr Paolo Morello Marchese ("**Recipient**") desires to engage in discussions and review Confidential Information (as defined below) relating generally to a study sponsored by **Inozyme Pharma, Inc.** ("**Sponsor**"), with its principal place of business at 321 Summer Street, Suite 400, Boston, MA 02210 USA, having the protocol: **INZ701 Program**, as may be amended from time to time (the "**Study**"). **Worldwide Clinical Trials Limited**, organized according to laws of England and Wales with its principal place of business at Fourth Floor, East West, Tollhouse Hill, Nottingham, NG1 5FS, UK together with its Affiliates (collectively "**Discloser**") desires to protect such Confidential Information from unauthorized use and disclosure and will only disclose such Confidential Information to the Recipient if Recipient agrees to the terms and conditions of this Agreement (this "**Agreement**"). Recipient and Discloser may hereinafter be individually referred to as a "**Party**" and collectively as the "**Parties**".

This Agreement is effective as of the date of the Recipient's signature below (the "**Effective Date**"). For purposes of this Agreement, "**Affiliates**" means any entity that controls, is under common control, or is controlled by a Party.

The Discloser will disclose Confidential Information to the Recipient's Principal Investigator, Dr Iacopo Olivotto (the "**Principal Investigator**"), who signs this Agreement for acceptance of the terms and conditions herein.

For good and valuable consideration including the contemplated contractual relationship with Discloser, the sufficiency of which is hereby acknowledged, Recipient herby agrees as follows:

1. Definition of Confidential Information. "**Confidential Information**" shall mean (i) all confidential and proprietary information in whatever form, used by, or belonging to, or relating to the Discloser or Sponsor or their Affiliates, officers, directors, employees, subcontractors, consultants, professional advisors or agents ("**Representatives**"), which is not generally known to the public or to the industry in which Discloser or any of the foregoing is or may become engaged in; (ii) all other information which Discloser advises the Recipient in writing should be treated as confidential, (iii) all copies and duplications of any such information, as well as any documents prepared by Recipient, which contain, incorporate by reference or reflect any Confidential Information of Discloser or Sponsor or their Representatives. Recipient acknowledges that no Recipient personal data governed by the European Union's ("**EU**") General Data Protection Regulation ("**GDPR**") or UK GDPR will be disclosed to Discloser or Sponsor in connection with this Agreement, unless necessary to accomplish the purpose of this Agreement. In cases of any such disclosure, Recipient represents that it has taken all necessary steps to assure that any such disclosure is made in compliance with the GDPR. Recipient acknowledges receipt of the Privacy Notice for site personnel ("**Privacy Notice**") attached to the Agreement as Appendix 1 and shall distribute the Privacy Notice to any of its Representatives or any other GDPR covered person disclosing personal data to Sponsor or Discloser under this Agreement

2. Nondisclosure and Non-Use Obligations. Recipient and Principal Investigator shall not disclose the Confidential Information to any third parties without the written consent of Discloser other than its Representatives, shall use such Confidential Information only to evaluate whether Recipient and Principal Investigator are interested in participating in the Study as a clinical study site or investigator, as applicable (the "**Purpose**"), shall not reverse engineer such Confidential Information and shall implement practices and procedures necessary to prevent such disclosure, which steps shall include at least those taken by Recipient to protect its own confidential information of like kind, but in no case less than a reasonable degree of care provided, however, that Recipient may disclose Confidential Information to Recipient's Affiliates and its Representatives (including any study team member under Recipient's supervision, study site personnel, or local ethics committee) who have a need to know, but only to the extent reasonably necessary to carry out the Purpose. Recipient (i) will

inform Representatives that such Confidential Information is confidential and is not to be disclosed to third parties, (ii) will ensure that Representatives who actually receive Confidential Information will be subject to nondisclosure and nonuse obligations substantially similar to those in this Agreement, and (iii) will be responsible for any noncompliance by Representatives.

3. Exclusions from Nondisclosure and Nonuse Obligations. The obligations of nondisclosure and nonuse in Section 2 shall not apply to any information which Recipient can show (a) was already known by Recipient before receiving such information from Discloser, (b) is or becomes known to the public or generally available to the public through no fault of Recipient, (c) is rightfully furnished to Recipient from a third party who to Recipient's knowledge is not under an obligation of nondisclosure or nonuse, (d) is independently developed by or for Recipient without use of Confidential Information, or (e) is approved for disclosure by Discloser. In the event Recipient is required by a valid order of a court or other governmental body or regulatory authority Recipient will provide Discloser with prompt notice (to the extent permitted to do so by applicable law) so that Discloser or Sponsor may seek a protective order or other appropriate remedy or waive compliance with the provisions of this Agreement.

4. Confidentiality. During the performance of this Agreement, the Discloser, Sponsor or their respective Representatives may gain access through site visits, investigator's meeting or other written or oral discussions to information relating to Recipient's business or research operations, policies, or procedures that Recipient identifies to Discloser, Sponsor and their respective Representatives as proprietary and confidential or that is reasonably apparent to Discloser, Sponsor or their respective Representatives to be so. Unless Receiving Party provides written consent, Discloser, Sponsor and their respective Representatives will not copy or remove such information, use such information for any purpose other than performance of this Agreement, or disclose such information to any third party except as required by applicable laws.

5. Ownership and Return of Confidential Information and Other Materials. All Confidential Information and any derivatives thereof shall remain the property of Discloser or Sponsor, and no license or other rights to such Confidential Information or derivatives is granted or implied hereby. No Confidential Information, including but not limited to employee contact information, shall be sold, assigned, licensed, or leased to third parties or commercially exploited by or on behalf of Recipient unless expressly authorized by Discloser in order to carry out the Purpose. Recipient shall return to Discloser, upon written request and at Discloser sole cost, all Confidential Information, as well as all excerpts, summaries, and photocopies, electronic copies, or other reproductions or extracts thereof, and work sheets and the like pertaining thereto; provided however, Recipient may retain one (1) archival copy of Confidential Information for the sole purpose of determining its obligations hereunder and one (1) electronic copy as part of its standard electronic back-up system.

6. Term. This Agreement shall terminate one (1) year from the Effective Date; provided, however, that obligations with respect to the Confidential Information contained herein shall expire five (5) years after the date of disclosure thereof to Recipient, provided, further, however, the Recipient agree that after the five (5) year period referenced above, any Confidential Information that is subject to other protection under applicable law (including, without limitation, patent, trademark, and copyright law) will continue to be subject to the protection of such laws notwithstanding the expiration of such five (5) year period.

7. No Other Obligations or Warranty. Nothing in this Agreement shall constitute or imply any obligation of Discloser to disclose any Confidential Information, to sell or purchase any product or service of Recipient, to refrain from selling or purchasing any product or service from any third party, or any commitment with respect to the present or future marketing of any product or service. No rights or obligations other than those expressly recited herein are to be implied from this Agreement. All Confidential Information is provided "AS IS" and without any warranty, express, implied or otherwise, regarding such Confidential Information's accuracy, completeness, or performance. Recipient accepts all risk of use of, and reliance on, Confidential Information.

8. Injunctive Relief. Recipient and Principal Investigator acknowledge that damages may be an

inadequate remedy in the event of a breach or intended or threatened breach by Recipient or Principal Investigator of this Agreement and that any such breach may cause Discloser or Sponsor irreparable injury and damage; accordingly, Recipient and Principal Investigator acknowledge that Discloser or Sponsor may be entitled to seek (without waiving, to the extent not prohibited by applicable laws, any additional rights or remedies, including monetary damages, otherwise available to Discloser or Sponsor at law, or in equity, or by statute) preliminary and permanent injunctive relief in the event of a breach or intended or threatened breach by Recipient.

9. Governing Law. This Agreement shall be governed and enforced in accordance with the laws of Italy, without reference to conflict of laws principles. Any claim, controversy or dispute arising under or related to this Agreement will be governed by the laws of Italy.

10. Counterparts; Electronic Signatures. In the event that any signature is delivered by e-mail delivery of a ".pdf" format data file or other electronic means, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such signature page were an original thereof. The Recipient agrees that its electronic signature is the legal equivalent of any handwritten signature and the Recipient consents to signing this Agreement by electronic means.

11. Third Party Beneficiary. Recipient acknowledges and agrees that Sponsor is an express and intended third party beneficiary of the terms and conditions of this Agreement such that Sponsor shall be entitled to enforce any of the provisions of this Agreement and exercise the rights of Sponsor or Discloser set forth herein.

12. Miscellaneous. Any provision of this Agreement that is determined by a court of competent jurisdiction to be invalid, illegal or unenforceable in any jurisdiction shall, as to that jurisdiction only, be ineffective to the extent of such invalidity, illegality or unenforceability, without affecting in any way the remaining provisions hereof in such jurisdiction or rendering that or any other provision of this Agreement invalid, illegal or unenforceable in any other jurisdiction. Any waiver of, or promise not to enforce, any right under this Agreement shall not be enforceable unless evidenced by a writing signed by the Discloser.

This Agreement shall inure to the benefit of and be binding upon the parties hereto, and their successors and assigns.

In the event this Agreement is translated for informational purposes, the Recipient hereby acknowledges and agree that the English version is the original language. In the event of a conflict of any purported inconsistency, the English version will prevail and shall be the binding version.

This Agreement constitutes the final, entire, and exclusive agreement concerning the subject matter of this Agreement and supersedes all prior agreements, understandings, negotiations and discussions, written or oral, between Recipient and Discloser and/or Sponsor with respect thereto. Any modification, rescission or amendment of this Agreement shall not be effective unless made in writing executed by both parties.

Each party agrees that it shall not make a public announcement of this Agreement, or any other agreement between the Parties, the discussions or the potential relationship, without the prior written consent of the other parties, except as may be required by any applicable law, rule or regulation of any governmental body.

This Agreement shall not be construed as evidence of an intention to enter into business relations or transactions.

The parties are independent contractors. This Agreement does not create any employment relationship, partnership or principal-agent.

IN WITNESS WHEREOF, the Recipient hereto acknowledges that the representative named below has the authority to execute this Agreement on behalf of the Recipient to legally bind the Recipient to the terms of this Agreement.

[SIGNATURES ON NEXT PAGE]

Dr. Iacopo Olivotto

Signature :

Title: MD

Date:

Address for notice:
Viale G. Pieraccini 24
50139 Firenze

Institution: Azienda Ospedaliera Universitaria Meyer - Istituto di Ricovero e Cura a Carattere Scientifico

Signature:

Print Name: Dr Paolo Morello Marchese

Title: CEO

Date:

Address for notice:
Viale G. Pieraccini 24
50139 Firenze

Worldwide Clinical Trials, Ltd.

_____
(Signature)

Print Name: _____

Title: _____

Date:_____

Address for notice:
4th Floor, East West
Tollhouse Hill, Nottingham, NG1 5FS, UK

Appendix 1
Privacy Notice for Site Personnel

The purpose of this Privacy Notice is to provide information concerning the collection and use of your personal data in relation to the **INZ701 Program** (the "Study") sponsored by **Inozyme Pharma, Inc.** ("Sponsor") and managed by its contract research organization Worldwide Clinical Trials ("Worldwide").

What personal data is collected?

In connection with the Study, personal data may be collected from members of the Study team by or on behalf of Sponsor or Worldwide, in particular:

- Name and contact details;
- Where applicable, your professional identification number;
- Office / practice location, type, amenities, contact and communication preferences
- Curriculum vitae, including any licenses, certifications and professional affiliations;
- Information about debarment and any professional discipline measures from government sources or professional organizations
- Declaration of financial interests, if applicable;
- Affiliation with a Site Management Organization ("SMO")
- Financial information collected for payment
- Historical and current information regarding participation and performance in clinical studies;
- Training records; and
- Authentication information for entering data into the eCRF (electronic case report form).

How is your personal data used?
The Sponsor of the study, who is the controller of the personal data described above, either itself or through a service provider (including Worldwide), may collect, process, store and use the personal data for the following purposes:

a) In preparation of a feasibility questionnaire, a clinical trial contract, collection of documents and other start-up activities in preparation of your participation in the Study;
b) To comply with legal regulations related to the Study
c) To review and assess your historical and current involvement in clinical trials and to contact you regarding participation in the Study or future studies.

Worldwide is a processor acting on behalf of the Sponsor for the above-mentioned purposes but it will also act as independent controller of the Investigator's personal data described above for the following limited purpose, for which you will be asked to provide your consent:

a) To review and assess your historical and current involvement in clinical trials and inviting you regarding participation in future studies.

To whom could the personal data be disclosed?

In connection with the above purposes, the Sponsor and Worldwide may disclose the personal data to the following categories of recipients:
a) Competent authorities (including in the context of product registration);
b) Third parties who process the personal data on behalf of the Sponsor (including Worldwide)
c) Sponsor and its affiliates who are involved in the Study
d) Third parties who process the personal data on behalf of Worldwide or Sponsor
e) Worldwide affiliates

In the rare cases the personal data may be used in connection with investigations or legal proceedings, in which case the personal data may be disclosed to law enforcement agencies or other governmental authorities. It may also be shared with the Sponsor or Worldwide's advisors in such matters.

In connection with any of the above purposes, the personal data may be transmitted to countries outside the European Union or United Kingdom, as applicable, which are not regarded as providing an adequate level of protection for personal data, such as the United States. In those cases, your personal data shall only be transferred where appropriate safeguards are in place to protect your personal data, such as EU Standard Contractual Clauses.

The Sponsor or Worldwide or their affiliated companies have agreements in place with the service providers who may have access to the personal data as described above, under which they are bound to keep your information confidential and not to use it for any other reason other than for the purposes described in this notice. The Sponsor's and Worldwide advisors are bound by obligations of professional secrecy.

In the event Sponsor or Worldwide decides to reorganize or divest our business through sale, merger, or acquisition, Sponsor or Worldwide may share personal information about you with actual or prospective purchasers.

Legal Basis for Processing:

The legal basis for the collection and use of the personal data is:

- Legitimate Interests: where the processing of your personal data is necessary for the purposes of the legitimate interest of the Sponsor, linked with the Study;
- Legal obligation: the processing is necessary to comply with a legal obligation imposed on the Sponsor (or on a third party acting on behalf of the Sponsor), linked with the Study;
- Consent: To review and assess your historical and current involvement in clinical trials and inviting you regarding participation future studies.

Personal Data Retention:

We will only retain your personal information for as long as necessary to fulfil the purposes we collected it for in connection with the Study. To determine the appropriate retention period for personal data, we consider the amount, nature, and sensitivity of the personal data, the potential risk of harm from unauthorized use or disclosure of your personal data, the purposes for which we process your personal data and whether we can achieve those purposes through other means, and the applicable legal requirements.

Data Security:

Sponsor and Worldwide have put measures put in place to protect the security of your information in accordance with the respective company's information security policies and procedures.

Sponsor and Worldwide have put in place appropriate security measures to prevent your personal information from being accidentally lost, used or accessed in an unauthorized way, altered or disclosed. Sponsor and Worldwide have put in place procedures to deal with any suspected data security breach and will notify you and any applicable regulator of a suspected breach where we are legally required to do so.

What are the rights to personal data?

Members of the study team are entitled at any time to access their personal data and/or, to the extent legally permissible, to have such information deleted or corrected or to object to the processing of the personal data or to request the restriction of the processing of the personal data. Such rights can be exercised by notifying Sponsor or Worldwide data protection teams at the following:

Inozyme Pharma, Inc.
321 Summer Street, Suite 400
Boston, MA 02210 USA

via email to Sponsor's Data Protection Representative at Inozyme.DPO@MyData-Trust.info

- **Worldwide Clinical Trials**
  4th Floor, East West
  Tollhouse Hill, Nottingham, NG1 5FS, UK
  Attn: Data Privacy Representative

  or via email to Worldwide's Data Protection Officer at dpo@worldwide.com.

Should you object to the processing of your personal data, we may still be required to process your personal data to comply with applicable law, but we will explain to you at the time you object to what processing activities will continue for legal compliance purposes.

Members of the study team are entitled to lodge a complaint with their local supervisory authority, easily identified through the following link: https://edpb.europa.eu/about-edpb/board/members_en