

AZIENDA OSPEDALIERO UNIVERSITARIA MEYER IRCCS

Determina del Dirigente n. 230 del 27-06-2024

Proposta n. 654 del 2024

Oggetto: AUTORIZZAZIONE ALLA CONDUZIONE DELLO STUDIO CLINICO NON-PROFIT DENOMINATO "ADALIMUMAB LEVELS IN INDUCTION CONTROL FOR CHRONIC ANTERIOR UVEITIS", COD. PROT. ADA LEVELS UVEITIS - APPROVAZIONE SCHEMI DI ACCORDO CON THE CHILDREN'S HOSPITAL OF PHILADELPHIA

Dirigente: FERRIGNO MARIANGELA

Struttura Dirigente: RESPONSABILE AFFARI GENERALI E SVILUPPO

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

DISPOSIZIONE DIRIGENZIALE

| | |
|------------------|---|
| Oggetto | Studio clinico |
| Contenuto | AUTORIZZAZIONE ALLA CONDUZIONE DELLO STUDIO CLINICO NON-PROFIT DENOMINATO “ADALIMUMAB LEVELS IN INDUCTION CONTROL FOR CHRONIC ANTERIOR UVEITIS”, COD. PROT. ADA LEVELS UVEITIS - APPROVAZIONE SCHEMI DI ACCORDO CON THE CHILDREN’S HOSPITAL OF PHILADELPHIA |

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|--------------------------------------|-----------------------------|
| Area Tecnico Amm.va | AREA TECNICO AMMINISTRATIVA |
| Coord. Area Tecnico Amm.va | BINI CARLA |
| Struttura | AFFARI GENERALI E SVILUPPO |
| Dirigente Proponente | MARIANGELA FERRIGNO |
| Responsabile del procedimento | ALESSIO FABBIANO |
| Immediatamente Esecutiva | SI |

| Conti Economici | | | |
|-----------------|-----------------|--------------|---------------|
| Spesa prevista | Conto Economico | Codice Conto | Anno Bilancio |
| | | | |
| | | | |

| Estremi relativi ai principali documenti contenuti nel fascicolo | | |
|--|------------|--|
| Allegato | N° di pag. | Oggetto |
| 1 | 12 | Schema accordo di trasferimento dati e materiale biologico |
| 2 | 13 | Schema accordo di sub-assegnazione del grant |



IL RESPONSABILE S.O.C. AFFARI GENERALI E SVILUPPO

(Dr.ssa Mariangela Ferrigno)

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...*”;

Dato atto che:

- 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;
- con deliberazione del Direttore Generale n. 286 del 09.05.2024 è stato adottato ai sensi dell’art. 50 novies comma 3 della L.R.T. 40/2005 e s.m.i., a seguito dei pareri favorevoli della Giunta Regionale e del Ministero della Salute, il Regolamento di organizzazione e funzionamento dell’A.O.U. Meyer I.R.C.C.S.;
- con deliberazione del Direttore Generale n. 296 del 10.05.2024 è stato approvato il nuovo assetto organizzativo dell’A.O.U. Meyer I.R.C.C.S. e che il nuovo organigramma avrà decorrenza dal 01 luglio 2024;

Dato atto altresì che nelle more della decorrenza del nuovo organigramma, continuano ad applicarsi le seguenti disposizioni organizzative:

- deliberazione del Direttore Generale n. 55 del 01.02.2021 con cui 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;
- deliberazione del Direttore Generale n. 56 del 01.02.2021 con cui 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;



- deliberazione del Direttore Generale n. 92 del 15.02.2021 con cui 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;

Richiamata la deliberazione del Direttore Generale n. 470 dell'8.11.2017, successivamente integrata con la deliberazione n. 211 del 30.04.2020, con il quale si è provveduto, a seguito delle azioni di sistematizzazione dell'organizzazione aziendale, alla declaratoria delle attività attribuite e/o delegate dal Direttore Generale ai singoli Responsabili delle Strutture Organizzative dello Staff della Direzione Generale, dello Staff della Direzione Amministrativa e dell'Area Tecnico Amministrativa, anche ai fini dell'adozione degli atti gestionali;

Dato atto che il Responsabile della S.O.C. Affari Generali e Sviluppo, Dr.ssa Mariangela Ferrigno, con riferimento alla presente procedura, attesta la regolarità amministrativa e la legittimità dell'atto;

Considerata la richiesta da parte del promotore The Children's Hospital of Philadelphia (CHOP), un ospedale senza scopo di lucro con sede a Philadelphia (Stati Uniti), per la conduzione dello studio clinico non-profit denominato "Adalimumab Levels in Induction Control for Chronic Anterior Uveitis", codice prot. ADA Levels Uveitis, che sarà eseguito presso la SOSA Reumatologia di questa Azienda sotto la responsabilità del Prof. Gabriele Simonini;

Atteso che per la conduzione del suddetto studio il CHOP ha proposto la stipulazione di un apposito Accordo di trasferimento dati e materiale biologico per disciplinarne i termini e le condizioni;

Considerato che lo studio riceve un contributo finanziario da parte della Childhood Arthritis and Rheumatology Research Alliance (CARRA), un'organizzazione non-profit con sede a Washington (Stati Uniti), e che pertanto si rende necessario stipulare anche un accordo con il CHOP per la sub-assegnazione all'AOU Meyer IRCCS di una quota del grant concesso dalla CARRA al CHOP per l'esecuzione delle attività di studio;

Preso atto che il Comitato Etico Regione Toscana - Pediatrico, nella seduta telematica del 11.06.2024, ha esaminato e approvato, con parere favorevole, il protocollo relativo allo studio in oggetto;

Verificato che dal presente atto non derivano oneri economici a carico dell'AOU Meyer IRCCS;

Visto il parere favorevole espresso dal Direttore Generale allo svolgimento dello studio in questione;

Ritenuto, pertanto, di autorizzare lo studio in oggetto e di approvare lo schema di Accordo di trasferimento dati e materiale biologico e lo schema di sub-assegnazione del grant da stipulare entrambi con The Children's Hospital of Philadelphia per la disciplina delle condizioni normative ed operative dello studio medesimo e per la disciplina della sub-assegnazione del grant, secondo gli schemi che, quali allegati N. 1 e N. 2 al presente atto, ne formano parte integrante e sostanziale;

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;

DISPONE

Per quanto esposto in narrativa che espressamente si richiama,



1. Di prendere atto del parere favorevole all'esecuzione dello studio in oggetto espresso dal Comitato Etico Regione Toscana- Pediatrico nella seduta del 11.06.2024.
2. Di autorizzare lo svolgimento dello studio di cui al punto precedente presso la SOSA Reumatologia.
3. Di approvare lo schema di Accordo di trasferimento dati e materiale biologico e lo schema di sub-assegnazione del grant da stipulare con The Children's Hospital of Philadelphia che, allegati rispettivamente N. 1 e N. 2 al presente atto, ne formano parte integrante e sostanziale.
4. Di dare atto che il Prof. Gabriele Simonini risulta essere il Responsabile dello studio di cui trattasi.
5. Di precisare che dal presente atto non derivano oneri economici a carico dell'AOU Meyer IRCCS.
6. 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 RESPONSABILE S.O.C. AFFARI GENERALI E SVILUPPO

(Dr.ssa Mariangela Ferrigno)

ANONYMIZED DATA AND MATERIAL TRANSFER AGREEMENT

This Data and Material Transfer Agreement (“Agreement”) is effective on the date of the last signature below (“Effective Date”) and is made between **The Children’s Hospital of Philadelphia**, a Pennsylvania nonprofit corporation with offices at 3401 Civic Center Boulevard, Philadelphia, PA 19104 (“CHOP”), and **Meyer Children’s Hospital IRCCS**, a public institution of the Italian Health Service with registered offices at Viale Gaetano Pieraccini 24, 50139 Florence, Italy (“Site”) (each a “Party” and collectively the “Parties”).

WHEREAS, the Parties are collaborating on a research project titled “Adalimumab Levels in Induction Control for Chronic Anterior Uveitis” (“Study”), which is the subject of a subaward agreement between the Parties being negotiated concurrent with this Agreement (“Subaward”); and

WHEREAS, to facilitate the performance of the Study, Site wishes to disclose certain Anonymized Data and Materials (each defined below) to CHOP; and

WHEREAS, Site is permitted to authorize the use or disclosure of the Anonymized Data and Materials by CHOP upon execution of the Subaward and this Agreement; and

WHEREAS, Site’s principal investigator is Prof. Gabriele Simonini (“**Site Principal Investigator**”), head of Site’s Rheumatology Department, and Prof. Melissa A. Lerman, Associate Professor in CHOP’s Division of Rheumatology, is the principal investigator at CHOP (“**CHOP Principal Investigator**”).

NOW, THEREFORE, in consideration of the mutual covenants contained in this Agreement and intending to be legally bound hereby, the Parties agree as follows:

SECTION 1: DEFINITIONS

- 1.01 “Anonymized Data” consists of personal data rendered anonymous in such a manner that the data are no longer identifiable pursuant to the standard for anonymization set forth in the data protection laws applicable to Site.
- 1.02 “Original Material” shall mean human blood samples and any additional progeny, unmodified derivatives, substances that could not have been made but for the Original Material, and any related information and know-how that is received by CHOP under this Agreement (collectively, the “Materials”).

SECTION 2: OBLIGATIONS AND ACTIVITIES OF CHOP

- 2.01 CHOP shall:
 - A. Not use or further disclose the Anonymized Data other than as permitted or required by this Agreement;
 - B. Use appropriate safeguards to prevent the use or disclosure of the Anonymized Data other than as provided for by this Agreement; and
 - C. Ensure that any agent, including a subcontractor, to whom CHOP provides the Anonymized Data received from Site agrees to the same restrictions and conditions that apply through this Agreement to CHOP with respect to such information.

- 2.02 CHOP may use the Anonymized Data for the Study as well as for other internal research and educational purposes. In addition, CHOP may share the Anonymized Data with Children’s Mercy Kansas City pursuant to the performance of the Study.
- 2.03 CHOP may use the Materials for the Study as well as for other internal research and educational purposes, in accordance with patient consent.
- 2.04 For clarity, CHOP may not use or disclose Anonymized Data or Materials for commercial purposes.
- 2.05 Legal title to the Anonymized Data and Materials will remain with Site. Each Party shall retain control of the Anonymized Data in its possession in accordance with the terms and conditions of this Agreement.
- 2.06 CHOP agrees that the Materials: (i) are to be used only at CHOP; (ii) will not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects without the written consent of Site (once Site has obtained the needed patient consents); and (iii) shall be used in accordance with all applicable U.S. federal, state and/or local laws, statutes, regulations, and guidelines.
- 2.07 In the event Site should decide to withdraw its consent to CHOP’s use of the Materials, it shall have a right to terminate this Agreement, upon thirty (30) days’ prior written notice to CHOP and CHOP Principal Investigator. CHOP will then destroy and not further use any Materials. Notwithstanding the foregoing, Anonymized Data and Materials already used and processed pursuant to the Study and/or other internal noncommercial research before Site’s withdrawal of consent may continue to be used for such research purposes.
- 2.08 The Parties plan that Anonymized Data will be stored in REDCap, and Materials will be stored in CHOP’s BioRepository Resource Center (BioRC). With respect to the storage of Materials in the BioRC, the Parties acknowledge that, as of the Effective Date, CHOP adopts the technical and organizational measures described in Exhibit C. Notwithstanding anything to the contrary herein, CHOP shall have the sole authority to determine whether any changes to its technical and organizational measures need to be made at any time. CHOP will retain the Anonymized Data and Materials for a period of ten (10) years following the Effective Date or the conclusion of the Study and other internal noncommercial research, whichever occurs first (“Retention Period”). CHOP will destroy any remaining Anonymized Data or Materials after the Retention Period has elapsed.

SECTION 3: OBLIGATIONS OF SITE

- 3.01 Site will comply with all applicable laws, rules, regulations, guidelines, standards, and industry best practices, including those relating to human subjects research, ethics committee oversight and approval, and the confidentiality, privacy and security of personal and patient data and all applicable policies of Site (collectively, “Applicable Laws”). Site represents and warrants that it is permitted under Applicable Laws to send the Anonymized Data to CHOP for the Study in accordance with this Agreement. Site will transfer to CHOP the Anonymized Data and provide other assistance with respect to the Study as described on Exhibit A. Site shall set forth in Exhibit

B any restriction to the use or disclosure of the Anonymized Data that Site has agreed to with an individual to the extent that such restriction would affect CHOP's use or disclosure of the Anonymized Data. For purposes of clarity, in the event the Anonymized Data was collected under clinical or research informed consent forms, relevant restrictions in such consent forms will be included in Exhibit B, if any. The foregoing restrictions are not intended to prohibit CHOP from publishing any results from the Study.

- 3.02 Site represents and warrants that it will send an Anonymized Data that meets the standard for anonymization set forth in the data protection laws applicable to Site, and has obtained all permissions, including without limitation obtaining any approvals relating to human subjects research, consents from or providing notices to data subjects required under the research and data protection laws applicable to Site to permit the transfer of the Anonymized Data to CHOP in the United States and the processing of the Anonymized Data by CHOP for the Study. To the extent required, Site will obtain approval from an ethics committee that complies with Site's applicable human subjects research laws and provide CHOP with a copy of such approval and any associated waiver, if applicable, or a determination that no such ethics committee approval is necessary.
- 3.03 Site certifies that the Anonymized Data and Materials provided pursuant to this Agreement were collected in accordance with the standard patient informed consent procedures of the Site in effect at the time of collection. Site certifies that it has the right to provide the Materials to CHOP.

SECTION 4: TERM; TERMINATION

- 4.01 This Agreement shall be effective as of the Effective Date and shall continue for as long as CHOP maintains any Anonymized Data or Materials provided by Site.
- 4.02 CHOP shall have the right to immediately terminate this Agreement if the Subaward or the Study is terminated.
- 4.03 Upon Site's knowledge of a pattern of activity or practice of CHOP that constitutes a material breach or violation of this Agreement, Site shall provide written notice of such material breach or violation, and CHOP shall attempt to directly cure, or cause the cure of, the material breach or end the violation within thirty (30) days of receipt of such notice. If CHOP has not cured, or caused the cure of, such material breach or violation within such thirty (30) day period, Site shall promptly terminate this Agreement, and discontinue disclosure of information to CHOP.

SECTION 5: MISCELLANEOUS

- 5.01 Use of Name. Neither Party shall use the name, insignia, trademark, trade name, logo, abbreviation, nickname, or other identifying mark or term of the other Party for any purpose, except as required by law, without the prior written consent of the other Party, provided however, that CHOP may use the name of Site in its routine listings of projects, as required on grant applications, and as required by scientific journals for publication. In the case of CHOP, Site shall obtain the prior written approval of CHOP's Chief Marketing Officer for each instance of use. Requests for such use shall be made to CHOP's Office of General Counsel at legal@chop.edu.

- 5.02 Survival. Sections 3, 4, and 5 herein shall survive the expiration or early termination of this Agreement.
- 5.03 Terms of Subaward. The rights and obligations expressed within this Agreement are in addition to any rights and obligations by and of the Parties expressed within the Subaward, and any terms contained in the Subaward not otherwise addressed in this Agreement shall govern the activities of the Parties hereunder. In the event of any conflict between the terms of the Subaward and the terms of this Agreement, the terms of this Agreement shall control.
- 5.04 Governing law and dispute resolution. Any dispute between the Parties relating to, arising from or, in any event, connected to this Agreement, its construction, performance, or termination shall be firstly attempted to be resolved amicably through informal negotiations. If no settlement or solution is amicably reached, the Parties agree to submit all disputes arising out of or in connection with this Agreement to the exclusive jurisdiction of the courts of the defending party; and, for the purposes of such proceeding, this Agreement shall be governed by, and shall be interpreted, construed, and enforced in accordance with the laws of the same jurisdiction.
- 5.05 Shipping costs. CHOP will cover costs associated with Materials shipping from Site to CHOP. No shipping costs shall be borne by Site.

[Signatures on Following Page]

CHOP and Site have caused this Agreement to be executed by their respective duly authorized officers. This Agreement shall be effective as of the Effective Date.

THE CHILDREN'S HOSPITAL OF PHILADELPHIA

By: _____

Name: Charles T. Bartunek, JD

Title: Sr. Director, Office of Collaborative and Corporate Research Contracts

Date: _____

CHOP PRINCIPAL INVESTIGATOR (Read & Acknowledged)

By: _____

Name: Melissa Lerman, MD PhD, MSCE

Title: _____

Date: _____

MEYER CHILDREN'S HOSPITAL IRCCS

By: _____

Name: Mariangela Ferrigno

Title: General Affairs and Development Dept. Manager

Date: _____

SITE PRINCIPAL INVESTIGATOR (Read & Acknowledged)

By: _____

Name: Prof. Gabriele Simonini

Title: _____

Date: _____

Exhibit A
Anonymized Data
Description

Demographics:

- Age
- Age at uveitis diagnosis
- Sex at birth

Disease information:

- Areas of additional involvement (int, post, pan, none)
- Granulomatous?
- Associate rheumatic disease
 - o None/idiopathic
 - o Sarcoidosis
 - o Inflammatory bowel disease
 - o Other
 - Specify:
 - o JIA
 - Oligo, persistent
 - Oligo, extended
 - Poly, rf-positive
 - Poly, rf-negative
 - Psoriatic
 - Enthesitis related
 - Systemic JIA
 - Undifferentiated
- ANA status

At drug initiation only:

Drug information

- MTX
 - o Concurrent Methotrexate use?
 - o Date of MTX start
 - o Started and stopped MTX previously?
 - o Other dmard?
 - Leflunomide
 - Mycophenolate
 - Azathioprine
 - No
- ADA
 - o Biosimilar?
 - If yes, specify:
 - o Previous TNFI?
 - Etanercept
 - Infliximab
 - Golimumab
 - Certolizumab
 - o Previous non-tnfi biologic?
 - Abatacept
 - Tocilizumab
 - Rituximab (or biosimilar)
 - Any jak/stat inhibitor
 - Other
 - Specify

- No
- Dosage at start
- Time between first two doses
 - 1 week
 - 2 weeks
 - Other
 - Specify
- Dosage at dose 2
- Frequency after dose 2
- Frequency after dose 3

At drug initiation and further visits:

- Provider visual analog scale
 - Ophthalmologist: How do you rate the patient's disease activity over the past week?
 - 0 (Not active) <-> 10 (active)
 - Rheumatologist: How do you rate the patient's disease activity over the past week?
 - 0 (Not active) <-> 10 (active)
- Is the child on ADA at the time of sample?
 - If not, does the child previously received ADA?
 - If discontinued, please state:
 - the reason
 - Date of last dose
 - Dosage at last dose
 - Frequency at last dose
- MTX information
 - Is patient on any of the following?
 - MTX
 - Mycophenolate
 - Leflunomide
 - Dosage of drug

At ophthalmology visits (initiation, months 1:6 of drug):

- Drop information (left and right)
 - Drops/day
 - Type of drops
- Eye exam (left and right)
 - Sun classification of anterior cell
 - Sun classification of flare
 - Intraocular pressure
 - Visual acuity
 - OCT?
 - If yes
 - Ocular edema present?
 - If yes
 - Worsening
 - Stable
 - Improving
 - Macular edema present?
 - If yes
 - Worsening
 - Stable
 - Improving
 - Optic nerve thickness

At rheumatology exam (initiation, months 2, 4, and 6):

- Active arthritis?
- Active enthesitis?
- Active psoriasis?
 - o Is psoriasis new?
- New rheumatic diagnoses?
 - o Specify:

Exhibit B
Anonymized Data Restrictions
Not Applicable

Exhibit C
BioRepository Resource Center Letter

[See next page]

*BioRepository Resource Center
The BioRC Operational Committee*

January 27, 2021

Dear Dr. Lerman,

We are writing to provide our enthusiastic support for your submission entitled "ADA Levels in Induction Control for Chronic Anterior Uveitis." After review of your grant proposal, the Biorepository Operational Committee (BOC) has determined your requested level of sample storage, sample tracking and required -80°C storage space are well within the capability of the Biorepository Resource Center (BioRC). Following IRB approval, the BioRC will provide storage for the samples collected through this study proposal.

The BioRC utilizes an Oracle-based tracking system called Nautilus which provides sample tracking for all stages of a study, including collection at the bedside, through processing and storage, following analysis and, if needed, sample distribution and shipping. Study-specific tracking is allowed after creating a unique study design for each project, which links all samples to the aliquots created following processing. This level of sample tracking would be available to your proposed study and can be provided by printing and providing label kits for each sample collection.

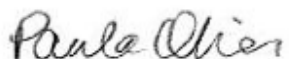
Investigators who utilize the BioRC are asked to commit to the Biobanking Principles at the time of BOC project review. We thank you for agreeing to the Principles, as this will help our BioRC to continue to benefit and expand its offerings to the Investigators, both collecting and requesting. The Principles specify that all human specimens collected for biobanking as part of a BioRC-supported project must be accessioned into the BioRC Nautilus Lab Information Management System (LIMS) following procedures established or reviewed by the Biorepository Operational Committee (BOC). In addition, specimen, clinical and derived data about the banked specimens will be generated and made available to Investigators through a centralized portal (Arcus). This data can be made available to CHOP Investigators based on a Data Sharing Agreement that is formulated before sample collections. The Collecting Investigator agrees to entertain collaborative requests to share specimens with the CHOP research community. Specimen sharing is encouraged, however, decisions on approving requests for specimen sharing/distribution are made by the Collecting Investigator.

The Biorepository Resource Center (BioRC) is well positioned to support your proposal. The BioRC was established in 2015 as part of the biobanking initiative at CHOP to support projects that complement its mission. The facility provides resources for both multi-institutional and investigator-specific biobanking programs at CHOP and facilitates integration and enhancement of access to information about biorepository resources, specimens and data across the CHOP community of investigators and also across the wider community of external investigators. BioRC assists investigators in developing new projects that require the collection and processing of samples, or to help existing projects whose investigators would like to migrate storage and management of their banked specimens and data to the BioRC. The BioRC is governed by an Operational Committee (BOC), which is made up of investigators, clinicians, and informatics professionals from multiple CHOP divisions (Pathology and Laboratory Medicine, Cardiology, Oncology, Allergy/Immunology & Infectious Disease, Neurology, and Biomedical Informatics), who have a wide variety of expertise. The BOC will be available to provide guidance to the BPC during its start-up phase and also throughout the duration of the project.

Currently, the BioRC supports various aspects of collection/accession, processing, storage, and distribution for 51 biobanking projects across the institute, including projects such as the Children's Brain Tumor Network biobank and the and the Prone and Oscillation Pediatric Clinical

Trial biobank, which are large multi-institutional biobanking efforts. The BioRC supported the collection, accession and banking of an additional 28,420 specimens into the biobank in 2019-2020. Currently the BioRC is tracking and/or storing approximately 258,147 specimens across a wide variety of specimen types, including tissue, blood, tissue blocks, DNA and RNA. The BioRC storage facility is located in a 2956 sq. ft. temperature controlled, card access facility in the Colket Translational Research Building. The BioRC storage facility includes a REMP Mid-Size Store (MSS) for storage of DNA samples. The REMP MSS holds up to 17,472 plates in 96 matrix tube formats, translating to 1.7 million DNA samples in a carefully monitored -20°C temperature and humidity-controlled environment. The BioRC also has storage capacity for 210,000 vapor phase liquid N2 (-196oC) samples and ~500,000 minus 80oC samples (RNA, tissue, plasma, serum, etc.). The BioRC is outfitted for expansion to accommodate liquid N2 storage of up to 300,000 samples and -80oC storage of up to 700,000 samples. Storage capacity of -80oC samples will be further increased to 1.5-2 million samples upon completion of the installation of a new robotic -80oC Hamilton Bios storage unit in June 2021. All specimens within the CHOP BioRC are tracked through the sophisticated Thermo Nautilus Laboratory Information Management System (LIMS). Nautilus LIMS is an enterprise Oracle-database LIMS system that facilitates tracking of specimens and specimen data through their functional lifetime, including acquisition, 2D-barcode labeling, storage, processing, testing, and QC.

In closing, the BioRC and BOC have both the infrastructure and expertise to facilitate a highly successful biospecimen coordinating center and we look forward to working with you on this important endeavor.



Paula M. Oliver, Ph.D.
Associate Professor
Chair, BioRC Operations Committee
Head, Division of Protective Immunity
Stokes Investigator
3615 Civic Center Boulevard
816F Abramson Research Center
267-426-2839 Office



David Stokes, Ph.D.
Director, BioRepository Resource Center (BioRC)
A340 Colket Translational Research Bldg.
3501 Civic Center Boulevard
Philadelphia, PA 19104-4399
215-590-4752 Office

Affiliated with the Perelman School of Medicine at the University of Pennsylvania

Subaward Agreement

| | | |
|--|---|--------------------------------------|
| Institution/Organization ("CHOP") Name: The Children's Hospital of Philadelphia Address: Roberts Center for Pediatric Research 2716 South Street, 15 th Floor Philadelphia, PA 19146-2305 USA CHOP's PI: Dr. Melissa Lerman | Institution/Organization ("COLLABORATOR") Name: Meyer Children's Hospital IRCCS Address: Viale Gaetano Pieraccini 24 Florence, Italy 50139 Collaborator's PI: Prof. Gabriele Simonini | |
| Prime Award No. N/A | Purchase Order No./Grant ID: Purchase Order #20408100 / Grant ID: GRT-00001994 | |
| Sponsor: <p style="text-align: center;">CARRA (Childhood Arthritis and Rheumatology Research Alliance)</p> | | |
| Subaward Period of Performance April 15, 2022 – April 14, 2025 | Amount Funded this Action <p style="text-align: center;">\$1,552.00 USD</p> | Est. Total (if incrementally funded) |
| Project Title: Adalimumab Levels in Induction Control for Chronic Anterior Uveitis | | |
| Reporting Requirements [Check here if applicable: <input checked="" type="checkbox"/> See Attachment 1] | | |
| Terms and Conditions | | |
| <p>1) CHOP hereby awards a cost reimbursable subaward, as described above, to Collaborator for the execution of the project "Adalimumab Levels in Induction Control for Chronic Anterior Uveitis" (the "Project" or "Study"). The statement of work and budget for this subaward are (check one): ___X___ as shown in Attachment 2. In its performance of subaward work, Collaborator shall be an independent entity and not an employee or agent of CHOP.</p> <p>2) CHOP shall reimburse Collaborator not more often than quarterly for allowable costs. Please forward all invoices to Chop.apinvoice@ipsservices.com or, if by hardcopy, to The Children's Hospital of Philadelphia, PO Box 2015, Secaucus, NJ 07096-2015, USA. Please reference Purchase Order No. 20408100 in order for invoices to be paid. Invoices that do not reference the PO number and Grant ID number shall be returned to Collaborator.</p> <p>3) A final statement of cumulative costs incurred, including cost sharing, marked "FINAL," must be submitted to CHOP's Financial Contact NOT LATER THAN sixty (60) days after subaward end date. The final statement of costs shall constitute Collaborator's final financial report.</p> <p>4) All payments shall be considered provisional and subject to adjustment within the total estimated cost in the event such adjustment is necessary as a result of an adverse audit finding against the Collaborator.</p> <p>5) Matters concerning the technical performance of this subaward should be directed to the appropriate party's Project Director, as shown in Attachment 3. Technical reports are required as shown above, "Reporting Requirements."</p> <p>6) Matters concerning the request or negotiation of any changes in the terms, conditions, or amounts cited in this subaward agreement, and any changes requiring prior approval, should be directed to the appropriate party's Administrative Contact, as shown in Attachment 3. Any such changes made to this subaward agreement require the written approval of each party's Authorized Official, as shown in Attachment 3.</p> <p>7) Each party shall be responsible for its negligent acts or omissions and the negligent acts or omissions of its employees, officers, or directors, to the extent allowed by law.</p> <p>8) Either party may terminate this agreement with thirty (30) days' written notice to the appropriate party's Administrative Contact, as shown in Attachment 3. Notwithstanding if the Sponsor terminates the Prime Award, CHOP will terminate in accordance with Sponsor requirements. Upon expiration of this subaward or early termination by either party, CHOP shall pay Collaborator on a pro rata basis for all Protocol milestones completed in accordance with the budget.</p> <p>9) This Agreement may be changed, amended, modified, extended or terminated by mutual consent provided that such consent shall be in writing and executed by the parties hereto prior to the time such change shall take effect. No-cost extensions require the approval of the CHOP. Any requests for a no-cost extension should be addressed to and received by the Administrative Contact, as shown in Attachment 3, not less than thirty days prior to the desired effective date of the requested change.</p> <p>10) The Subaward is subject to the terms and conditions of the Prime Award in Attachment 4, and other special terms and conditions, as identified in Attachment 1.</p> | | |
| By an Authorized Official of CHOP: | By an Authorized Official of COLLABORATOR: | |
| _____ | _____ | |

Carrie S. Andrews, JD
Manager, Sponsored Projects

Date

Dr Mariangela Ferrigno
General Affairs and Development Dept.
Manager

Date

**Attachment 1
Subaward Agreement
Reporting Requirements And Special Terms and Conditions**

1. PROGRESS REPORTS. Reports of all programmatic findings related to the project will be sent to the CHOP PI when requested. Reports should be in the format requested by the CHOP PI. COLLABORATOR will provide CHOP with documentation necessary to complete any additional reports required by CHOP (such as regulatory approvals and assurances, program income, or invention statements).

2. GENERAL CONDITIONS. This agreement will be administered in compliance with the provisions herein and COLLABORATOR agrees to comply with all applicable laws, regulations and policies pertaining to COLLABORATOR'S performance hereunder, and any other laws, regulations, policies specifically referenced in this Agreement as they may be amended from time to time. Costs, compensation and invoices must be expressed in U.S. dollars using an exchange rate applicable at the time the invoice is submitted (hereinafter, "Dollars" or "\$").

3. SPECIAL CONDITIONS.

a. Inventions, Patents, Copyrights and Data. Inventions: CHOP shall own all right, title and interest in and to any and all inventions and/or discoveries developed solely by CHOP staff utilizing COLLABORATOR'S facilities during the course of the performance of the services in this Agreement. Any invention shall be promptly disclosed in writing to the other party. COLLABORATOR agrees to grant a non-exclusive, royalty-free license to CHOP to utilize any invention for internal research purposes.

b. Copyrights: Disposition of any copyrights or any copyrightable material produced under the performance of this agreement by COLLABORATOR will be determined by the COLLABORATOR's policy. Copies of all copyrighted or copyrightable materials will be provided to the CHOP PI.

c. Data: COLLABORATOR will own the data it generates under this Agreement; provided, however, that CHOP will have the right to receive copies of such data and use such data for any purpose provided it is in accordance with the signed Informed Consent Form ("ICF"), the authorization form, and applicable laws.

d. Publication, and Acknowledgment of Support. Publications generated from the work to be performed under this Agreement will identify and credit participation by the CHOP PI and the COLLABORATOR PI and authorship will be determined by written agreement between the COLLABORATOR PI and the CHOP PI based upon contributions made in accordance with standards of scholarly publications. All publications, reports and other materials resulting from the Study will acknowledge Sponsor's support. All publications and presentations resulting from this award are subject to the current CARRA Publications and Presentations Policy, which is available on the CARRA website, as per the Prime Award.

4. USE OF NAME. CHOP and COLLABORATOR each agree not to use the name of the other, or the name of any staff of the other, in news releases, commercial or non-commercial advertising or in other publications (with the exception of scholarly publications, without the prior written permission of a duly authorized officer of the other party and the affected individual (if any).

5. ENTIRE AGREEMENT. This Agreement constitutes the entire agreement and understanding between CHOP and COLLABORATOR. It merges all prior discussions between the parties and neither party will be bound by conditions, definitions, warranties, understanding or representations concerning such subject matter except as provided in this Agreement. Any changes or modifications to this Agreement or to any attachment to this Agreement will be made in writing and executed by the duly authorized representatives of CHOP and COLLABORATOR.

6. ASSURANCES AND CERTIFICATIONS.

Protection of Human Subjects. COLLABORATOR will comply with all requirements relating to human subject protections as set forth at 45 C.F.R. Part 46 and 21 C.F.R. Part 50 (Protection of Human Subjects) to the extent applicable to COLLABORATOR which is established outside the United States. COLLABORATOR will comply with all national, European and international laws and regulations applicable to it in the conduct of the Project and clinical studies.

COLLABORATOR agrees that it will obtain the approval of its institutional review board (the "IRB") – Ethics Committee - prior to conducting any studies involving human subjects and will comply with all IRB policies and requirements regarding such research.

COLLABORATOR will notify CHOP immediately if IRB approval of the Study has to be revoked or suspended for any reason.

COLLABORATOR declares that the cognizant IRB is in full compliance with all relevant federal regulations.

COLLABORATOR further agrees to notify CHOP immediately of any actions taken by the competent government authority in relation to the IRB.

Unanticipated events, drug reactions, or other reports of project activity that could assist CHOP and other collaborators, if any, in protecting the health or safety of study subjects will be immediately reported to the CHOP PI, in addition to reporting to the extent required to the FDA, as applicable.

By signing this Agreement, COLLABORATOR certifies:

Debt. That it is not delinquent in repaying any federal debt to the United States of America ("U.S."). If the applicant discloses delinquency on a debt owed to the U.S. federal government, the subaward may not be awarded until the debt is satisfied or satisfactory arrangements are made with the agency to which the debt is owed.

Debarment and suspension. Institution IS NOT subject to the debarment or suspension certification requirement or to debarment or suspension under 45 CFR Part 76, http://www.access.gpo.gov/nara/cfr/waisidx_00/45cfr76_00.html. ALL OTHER FOREIGN RECIPIENTS AND INTERNATIONAL ORGANIZATIONS ARE SUBJECT TO THESE REQUIREMENTS.

Drug-free workplace. Compliance with the Drug-Free Workplace Act of 1988 (Public Law 100-690, Title V, Subtitle D, as amended) requires that all organizations receiving grants from any federal agency agree to maintain a drug-free workplace, http://grants2.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part4.htm#_Toc54600067. [NOTE: Foreign applicants and grantees may be exempted from the drug-free workplace requirements of 45 CFR Part 76 based on a documented finding by the NIH awarding office that application of those requirements is inconsistent with U.S. international obligations or the laws and regulations of a foreign government].

Assurances. That it is in compliance with all laws and regulations governing the protection of human subjects. No activities involving human subjects will occur under this Agreement until Sponsor receives approval of the Project from Sponsor's appropriate Institutional Review Board.

7. CUSTOMS/IMPORT DUTIES/TRAVEL COSTS. Customs and Import Duties are unallowable. This includes consular fees, customs surtax, value-added taxes, and other related charges. Travel costs are limited to those allowed by formal organizational policy and, in the case of air travel, the lowest reasonable commercial airfares must be used.

8. GOVERNING LAW AND LANGUAGE. Any dispute relating to, arising from or in any event, connected to this Agreement, its construction, performance, or termination shall be firstly attempted to be resolved amicably through informal negotiations; if no settlement or solution is amicably reached, the parties hereby agree to submit all disputes arising out of or in connection with this Agreement to the exclusive jurisdiction of the courts of the defending party; and, for the purposes of such proceeding, this Agreement shall be governed by, and shall be interpreted, construed, and enforced in accordance with the laws of the same jurisdiction..

In the event that a translation of this Agreement is prepared and signed by the parties, and a conflict arises between the English version and other language version, this English language version shall be the official version and shall govern and control. The Parties acknowledge that CHOP is subject to the laws of the United States. The parties hereby agree that nothing in this Agreement or any of its attachments or references shall be deemed to require either Party to breach any mandatory statutory law under which each Party is operating.

10. ANTI-TERRORIST COMPLIANCE. Institution hereby agrees that all funds, including funds provided to any subcontractors, will be used in compliance with all applicable United States anti-terrorist financing and asset control laws, regulations, rules and executive orders.

11. EXPORT CONTROLS. It is understood that CHOP is subject to United States laws and regulations controlling the export of technical data, computer software, laboratory prototypes and other commodities, and that its obligations hereunder are contingent on compliance with applicable U.S. export laws and regulations . The transfer of any such technology and items and the entering into and provision of such transactions and services that are subject to restrictions may require a license or authorization from the cognizant agency of the United States Government, and/or may require written assurances by the receiving party that it shall not re-export such technology and items to certain foreign destinations and/or to certain recipients without prior approval of the cognizant government agency, and/or may require that the involved individuals and entities will comply with conditions on transactions and services. While CHOP agrees to cooperate in securing any license which the cognizant agency deems necessary in connection with this Agreement, CHOP cannot guarantee that such licenses will be granted.

Each party is responsible for determining whether its performance is subject to, and in compliance with, U.S. export control laws and regulations ("U.S. Export Controls"), including but not limited to the Export Administration Regulations - EAR (Department of Commerce), the International Traffic in Arms Regulations - ITAR (Department of State), the sanctions programs embodied in regulations administered by the Department of the Treasury's Office of Foreign Assets Control (OFAC), the U.S. anti-boycott laws and regulations (EAA) and U.S. anti-terrorism financing laws and regulations.

12. FOREIGN CORRUPT PRACTICES. The Parties agree to use funds in compliance with (1) the U.S. Foreign Corrupt Practices Act; (2) The Parties agrees that, under this Agreement, they will not offer, promise, or provide (or authorize the offer, promise, or provision of), directly or indirectly, anything of value to any government official, political party official, political candidate, or employee thereof, or to any other third party, for the purpose of obtaining or retaining business or obtaining any illegal benefit or advantage.

**Attachment 2
Subaward Agreement
Statement of Work and Budget**

**EXHIBIT A:
BUDGET AND PAYMENT SCHEDULE**

Protocol Title: Adalimumab Levels in Induction Control for Chronic Anterior Uveitis

Site Investigator: Gabriele Simonini

Site of Performance: Azienda Ospedaliero-Universitaria Meyer (Meyer Children’s Hospital IRCCS)

Project Period:04/15/2022-04/14/2024

| TABLE B2 – Per Subject Payment Schedule | | | | |
|---|--|---|--|---------------|
| | Activity | Payment After | Cost Breakdown | Amount |
| Coordinator Effort | Research coordinator/associate time to bring patient to lab, arrange for proper blood collection storage, enter data and prepare outbound shipping of samples to CHOP. | Receipt of blood sample and entry of visit data in REDCap eCRF.Details: 50% upon data entry and 50% on sample acquisition | \$20/hr.*3hr/study visit*3 per patient | \$180 |
| Lab Testing & Shipping | ADA and ADA Ab levels assessed at month 2 and 4 | | | Paid by CHOP |
| Total Direct | | | | \$180 |
| Indirect Cost | | | | \$14 |
| Total Per Patient | | | | \$194.00 |

Scope of Work

Site will enroll patients in the Study who are diagnosed with non-infectious CAU (juvenile idiopathic arthritis associated or other) and have recently started ADA.

Each patient should be recruited within 2 months of starting ADA at standard of care visits for uveitis.

Each patient will have bloodwork drawn for the study at three time points: 2, 4 and 6 months after starting ADA.

Labs should be drawn 48 hours before a dose of ADA is due (trough).

Specimens should be processed and stored frozen at Site.

Specimens should be shipped at CHOP’s expense every 6-8 months to CHOP for analysis.

During the visits, the site is required to fill out information regarding the patient in Redcap, including demographic information and baseline data.

**Attachment 3
Contact Information**

| CHOP's Contacts | Collaborator's Contacts |
|---|--|
| <p>Administrative Contact</p> <p>Name: Carrie S. Andrews, JD, Manager, Sponsored Projects Address: Roberts Center for Pediatric Research 2716 South Street, 15th Floor Philadelphia, PA 19146-2305</p> <p>Telephone: 267-426-7810 Fax: 215-590-3804 Email: subawards@chop.edu / andrewsc@chop.edu</p> | <p>Administrative Contact</p> <p>Name: Alessio Fabbiano Address: Meyer Children's Hospital IRCCS Viale Gaetano Pieraccini 24 Florence, Italy 50139</p> <p>Telephone: +390555662054 Fax: N.A. Email: alessio.fabbiano@meyer.it</p> |
| <p>Principal Investigator</p> <p>Name: Dr. Melissa Lerman Address: The Children's Hospital of Philadelphia 3500 Civic Center Blvd Philadelphia, PA 19104</p> <p>Telephone: 215-384-5710 Fax: Email: lermanm@chop.edu</p> | <p>Project Director</p> <p>Name: Prof. Gabriele Simonini Address: Meyer Children's Hospital IRCCS Viale Gaetano Pieraccini 24 Florence, Italy 50139</p> <p>Telephone +390555662054 Fax: N.A. Email: gabriele.simonini@unifi.it</p> |
| <p>Financial Contact</p> <p>Name: Steve Wiley, Director of Research Finance Address: The Wanamaker Building 100 East Penn Square, 6th Floor Philadelphia, PA 19107</p> <p>Telephone: +1 215-590-3802 Fax: Email: CHOP.APINVOICE@IPSSERVICES.COM</p> | <p>Financial Contact</p> <p>Name: Alessio Fabbiano Address: Meyer Children's Hospital IRCCS Viale Gaetano Pieraccini 24 Florence, Italy 50139</p> <p>Telephone: +390555662054 Fax: N.A. Email: alessio.fabbiano@meyer.it</p> |
| <p>Authorized Official:</p> <p>Name: Carrie S. Andrews, JD, Manager, Sponsored Projects Address: Roberts Center for Pediatric Research 2716 South Street, 15th Floor Philadelphia, PA 19146-2305</p> <p>Telephone: 267-426-7810 Fax: 215-590-3804 Email: subawards@chop.edu</p> | <p>Authorized Official</p> <p>Name: Mariangela Ferrigno Address: Meyer Children's Hospital IRCCS Viale Gaetano Pieraccini 24 Florence, Italy 50139</p> <p>Telephone: +390555662310 Fax: Email: mariangela.ferrigno@meyer.it</p> |

**Attachment 4
Prime Award**



March 14, 2022

Melissa A. Lerman, MD PhD
Children's Hospital of Philadelphia

Ashley M. Cooper, MD
Children's Mercy Kansas City

Re: CARRA-Arthritis Foundation Large Grant Application
Project Title: *Adalimumab Levels in Induction Control for Chronic Anterior Uveitis*

Amount awarded: \$ [REDACTED]
Project period: April 15, 2022 – April 14, 2024

Dear Dr. Lerman and Dr. Cooper,

I am pleased to share that your CARRA-Arthritis Foundation Large Grant application has been approved. All grant proposals received were evaluated by members of the CARRA Scientific Review Committee (SRC) and their rankings and feedback were then provided to the CARRA Internally Funded Research Oversight Committee (IROC). A summary statement with reviewers' comments is attached.

Funding

CARRA provides funds to the submitting institution in a lump sum payment to be used by the PI according to the needs for this project and in accordance with the approved budget included with the proposal. Funds will be released to the institution contact provided in the application upon receipt of the following items:

- Submitting institution W-9
- Headshot photo of the PI for communication purposes (CARRA website, newsletter, announcements, etc.)
- Fully signed Award Acceptance Form
- IRB approval documentation, if applicable

Please return the above items to grants@carragroup.org as soon as possible.

By accepting this award you agree to:

- Provide a final progress report required upon completion of the project or at the end of the two-year project period, whichever occurs first. You will be provided with the progress report template.
- Submit an abstract and prepare a poster based on any preliminary results of your project at the 2023 CARRA annual meeting (date and location TBA).
- Provide copies of all future publications resulting from this project. All publications and presentations resulting from this award are subject to the current CARRA Publications and Presentations Policy, which is available on the [CARRA website](#). This includes acknowledgement of CARRA and the Arthritis Foundation on all publications/presentations. You can find current logos and slide templates on the CARRA website as well.

If the project is not completed within the project period, you may request a one-time no-cost extension (NCE) for up to 12 months. You must submit a No-Cost Extension Request Form no more than 90 days prior, and no

555 East Wells St. 1100 | Milwaukee, WI 53202 | 414.918.9822 | info@carragroup.org



less than 30 days prior, to the project period end date and include a satisfactory plan for completion. An interim progress report is required as part of the no-cost extension request. Templates for these forms are available on the [CARRA website](#). Send your NCE request to the CARRA Grants Manager at grants@carragroup.org.

If you are unable to complete the project, any unexpended balance must be returned to CARRA.

Finally, the CARRA Early Investigator workgroup offers 2 resources that can support your future grant applications:

1. [Specific Aims Review Sessions](#) to be held quarterly. At these sessions, EIs can get feedback on their drafted aims pages from senior CARRA investigators.
2. [Research Development Program \(RDP\)](#) provides drop-in coaching to help identify unmet needs and additional support for your grant applications. The RDP can help you with developing hypotheses, identifying mentors, study design, budgeting and more! Please click [here](#) to sign up.

E-mail Kaveh Ardalan (kaveh.ardalan@duke.edu) and Sabrina Gmuca (gmucas@chop.edu) if you would like to submit an aims page, review aims pages, or have any questions about these programs!

We appreciate your prompt response to this letter. If you have any other questions, please don't hesitate to ask.

Regards,

Jennifer Kowalski
Assistant Executive Director, CARRA
(414) 918-9822
jkowalski@carragroup.org





Childhood Arthritis and Rheumatology Research Alliance

CARRA-Arthritis Foundation Award Acceptance Form



| | |
|--|---------------------------------------|
| Principal Investigator: Melissa Lerman and Ashley Cooper | |
| Institution: Children's Hospital of Philadelphia | |
| Grant Type: Large Grant | Grant Application Date: 10/01/2021 |
| Project Period: 04/15/2022 – 04/14/2024 | Approved budget: \$ [REDACTED] |
| Title of Project: Adalimumab Levels in Induction Control for Chronic Anterior Uveitis | |

The following institutional contact information was provided in the application. If any of the information below is has changed, please update.

| Grants/Sponsored Programs Contact | Financial Contact | Funds Receivable Contact |
|---|---|---|
| Name: Amna Raja Email: rajaa@chop.edu Phone: 215-590-4876 | Name: Steven Wiley Email: stokes@chop.edu Phone: (267) 426-0122 | Name: Steven Wiley Email: stokes@chop.edu Phone: (267) 426-0122 Address: Lockbox #1457, CHOP Research Institute, PO Box 8500, Philadelphia PA 19178-1457 (Street, Suite, City, State, Zip) |

The principal investigator must sign this form indicating that s/he has accepted the above indicated grant and will abide by the requirements outlined in the award letter. No funds will be disbursed to the institution until this acceptance form is received by CARRA, with any other requested documentation.

REQUIRED SIGNATURE

| | |
|--|---|
| NAME OF PRINCIPAL INVESTIGATOR (please print): Melissa Lerman | TITLE: Principal Investigator |
| SIGNATURE:  <small>Melissa Lerman (Mar 30, 2022 06:32 EDT)</small> | DATE: Mar 30, 2022 |
| NAME OF INSTITUTION OFFICIAL (please print): Raylonda V. King, | TITLE: Manager PreAward Administration |
| SIGNATURE:  | DATE: Mar 30, 2022 |

Return this form to the CARRA Grant Administrator at grants@carragroup.org.

555 East Wells St. 1100 | Milwaukee, WI 53202 | 414.918.9822 | info@carragroup.org
carragroup.org



Address of Institution office to which checks should be mailed as provided in the original application indicated below (make updates if this information is incorrect):

Checks payable to: CHOP Research Institute

Attention of (office): Specialized Accounting / PI: Melissa Lerman

Building/Room Number: Lockbox #1457,

Street Address: PO Box 8500,

City, Street, Zip: Philadelphia, PA 19178-1457

Phone Number: (267) 426-0122

Return this form to the CARRA Grants Manager at grants@carragroup.org.

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carragroup.org