

<p>This Agreement is drafted in both English and Italian. The English version shall supersede the Italian version.</p>	<p>Il presente Contratto è redatto in lingua inglese e italiana. La versione in lingua inglese prevarrà su quella in lingua italiana.</p>
<p>This master research agreement is between Azienda Ospedaliera Universitaria Policlinico “PAOLO GIACCONE” represented by its General Manager ,Dr. Maria Grazia Furnari, and, UNIVERSITY HEALTH NETWORK, an Ontario corporation (“Institution”) and DR. EWAN GOLIGHER, an individual appointed at Institution (“UHN Investigator”). Site, Institution and UHN Investigator are each a “Party” and are collectively the “Parties”.</p>	<p>Il presente Accordo Quadro di Ricerca è stipulato tra Azienda Ospedaliera Universitaria Policlinico Paolo Giaccone in persona della Direttrice Generale Dott.ssa Maria Grazia Furnari e UNIVERSITY HEALTH NETWORK, una società dell'Ontario (“Istituzione”) e il DR. EWAN GOLIGHER, una persona fisica nominata presso l'Istituzione (“Ricercatore dell'UHN”) in data [inserire data]. Il [SITE], l'Istituzione e il Ricercatore dell'UHN sono definite individualmente una "Parte" e collettivamente le "Parti".</p>
<p>Background/Recitals: Institution and UHN Investigator have developed a registry embedded adaptive clinical trial platform entitled the Practical Platform@UHN governed by the master protocol entitled “Platform of Randomized Adaptive Clinical Trials in Critical Illness (PRACTICAL) Randomized Controlled Trial” (Protocol #OZUHN-004), a copy of which is attached hereto as Schedule A and, together with its amendments, incorporated herein by reference (“Master Protocol”). Under the platform described in the Master Protocol (“Project Platform”), multiple studies will be conducted and are referred to in the Master Protocol as domain protocols (each is a “Study”, and its related protocol is a “Study Protocol”). For each Study that investigators at Site wish to participate in, the Site, Institution and their respective investigators who wish to conduct the Study will execute a study order incorporating the terms of this agreement and the additional terms applicable the Study Protocol (each is a “Study Order”). The project described in the Master Protocol is referred to as the “Project” and includes any Studies conducted under the auspices of the Project. The term “Protocol” refers to the applicable research protocol as the context requires whether it is the Master Protocol or one of the Study Protocols. The term “Agreement” refers to this master research agreement including its amendments and any Study Orders entered into among the Site and Institution.</p>	<p>Quadro di riferimento/premessa: L'Istituzione e il Ricercatore dell'UHN hanno sviluppato una piattaforma di sperimentazione clinica adattiva integrata nel registro, denominata Practical Platform@UHN, regolata dal Protocollo Generale intitolato "Platform of Randomized Adaptive Clinical Trials in Critical Illness (PRACTICAL) Randomized Controlled Trial" (Protocollo #OZUHN-004), una copia del quale è allegata al presente documento come Allegato A e, con le relative modifiche, incorporata nel presente per riferimento (“Protocollo Generale”). Nell'ambito della piattaforma descritta nel Protocollo Generale (“Piattaforma del progetto”), saranno condotti numerosi studi, indicati nel Protocollo Generale come protocolli specifici (ciascuno è uno “Studio”, e il relativo protocollo è un “Protocollo dello Studio”). Per ogni Studio a cui i ricercatori del [SITE] desiderano partecipare, il [SITE], l'Istituzione e i rispettivi ricercatori che desiderano condurre lo Studio sottoscriveranno una Richiesta di Studio che incorpora i termini del presente accordo e i termini aggiuntivi applicabili al Protocollo dello Studio (ciascuno è una “Richiesta di Studio”). Il progetto descritto nel Protocollo Generale è indicato come “Progetto” e include tutti gli studi condotti sotto gli auspici del Progetto. Il termine “Protocollo” si riferisce al protocollo di ricerca applicabile, come richiesto dal contesto, sia che si tratti del Protocollo Generale o di uno dei Protocolli degli studi. Il termine “Accordo” si riferisce al presente Accordo Quadro di Ricerca, incluse le relative modifiche e gli</p>

<p>The UHN Investigator is appointed to the research staff of Institution. Institution is an academic health sciences centre located in Toronto, Ontario, Canada.</p> <p>The AOUP Paolo Giaccone is home to the School of Medicine and Surgery of the University of Palermo in addition to the hospital-type care function, teaching and scientific research activities are carried out, located in Palermo, Italy]. For each Study, Site will identify an individual appointed to the research staff of Site to act as the investigator at Site AOUP Researcher Prof. Andrea Cortegiani</p> <p>Institution has engaged Istituto Di Ricerche Farmacologiche Mario Negri IRCCS, an Italian not-for-profit research foundation (“Contractor”) to engage with Regulatory Authorities and coordinate the Study in Italy, and Ozmosis Research Inc., a Canadian contract research organisation (“CRO”) to monitor the Study.</p> <p>The Parties wish to set out the terms on which the Site and each Site Investigator will participate in the Project and in one or more Studies.</p>	<p>eventuali Richieste di Studio stipulati tra il [SITE] e l'Istituzione.</p> <p>Il Ricercatore dell'UHN è nominato all'interno dello staff di ricerca dell'Istituzione. L'Istituzione è un centro accademico di scienze della salute situato a Toronto, Ontario, Canada. L'AOUP Paolo Giaccone è sede della scuola di Medicina e Chirurgia dell'Università degli Studi di Palermo oltre alla funzione assistenziale di tipo ospedaliero, vengono svolte attività di didattica e ricerca scientifica, situata a Palermo in Italia. Per ogni Studio, il [SITE] identificherà una persona fisica nominata all'interno dello staff di ricerca del [SITE] per agire come sperimentatore presso l'AOUP] "Ricercatore Prof. Andrea Cortegiani".</p> <p>L'Istituzione ha incaricato l'Istituto Di Ricerche Farmacologiche Mario Negri IRCCS, una fondazione di ricerca italiana senza scopo di lucro ("Contraente") di impegnarsi con le Autorità di regolamentazione e coordinare lo Studio in Italia, e Ozmosis Research Inc. un'organizzazione di ricerca a contratto canadese ("CRO") di monitorare lo Studio.</p> <p>Le Parti intendono definire i termini in base ai quali il [SITE] e ciascun Ricercatore del [SITE] parteciperanno al Progetto e a uno o più Studi.</p>
<p>The Parties agree as follows:</p>	<p>Le Parti concordano quanto segue:</p>
<p>1. Conduct of the Research</p> <p>1.1. Site and Site Investigator agree to carry out their responsibilities in the Master Protocol in accordance with this Agreement. Each Study will contribute data to the Project as set out in the Master Protocol for uses that include determining eligibility for other Studies. No Study will be conducted at Site without the approval of Site and Site Investigator and the signature of a Study Order.</p>	<p>1. Conduzione della Ricerca</p> <p>1.1. Il [SITE] e il Ricercatore del [SITE] si impegnano a esercitare le responsabilità imposte loro dal Protocollo Generale in conformità con il presente Accordo. Ogni Studio contribuirà con l'apporto di dati al progetto, come stabilito nel Protocollo Generale, per usi che includono la determinazione dell'idoneità per altri studi. Affinché uno Studio possa essere condotto presso il [SITE] sarà necessaria l'approvazione del [SITE] e del Ricercatore del [SITE], nonché la firma di una Richiesta di Studio.</p>
<p>1.2. Each Study will be the subject of a Study Order that will be incorporated into this Agreement. The investigator</p>	<p>1.2. Ogni Studio sarà oggetto di una Richiesta di Studio che sarà incorporato nel presente Accordo. Il ricercatore</p>

<p>named in the Study Order shall have all the rights and obligations of the Site Investigator and as a Party hereunder for the purposes of that Study Protocol. Site and its Site Investigator as applicable to each Study or Protocol are together referred to as “Researchers”. A sample Study Order is attached as Schedule B to this Agreement and will be customized and negotiated as appropriate to each Study.</p>	<p>indicato nella Richiesta di Studio avrà tutti i diritti e gli obblighi del Ricercatore del [SITE] e come Parte del presente documento ai fini di tale Protocollo dello Studio. Il [SITE] e il Ricercatore del [SITE], come applicabile a ciascuno Studio o Protocollo, sono insieme indicati come “Ricercatori”. Un esempio di Richiesta di Studio è allegato come Allegato B al presente Accordo e verrà personalizzato e negoziato in base alle esigenze di ciascuno Studio.</p>
<p>1.3. The Project is governed by a committee structure outlined in the Master Protocol. Site Investigator may submit protocols for incorporation into the Project in accordance with the policies of the Project. Project policies will be provided under separate cover or may be accessed through the Project website.</p>	<p>1.3. Il Progetto è disciplinato da una struttura di comitati delineata nel Protocollo Generale. Il Ricercatore del [SITE] può presentare protocolli da incorporare nel Progetto in conformità con le politiche del Progetto. Le politiche del Progetto saranno fornite in separata sede oppure possono essere consultate attraverso il [SITE] web del Progetto.</p>
<p>1.4. Each Party will carry out their respective responsibilities (i) as set out in the Protocol, as amended and approved by all applicable research ethics boards, and (ii) in accordance with all applicable laws, government regulations and guidelines including but not limited to the ICH Harmonised Tripartite Good Clinical Practice Consolidated Guideline (ICH/GCP Guideline), the Declaration of Helsinki and in accordance with generally accepted clinical practices. No Party promises success in achieving any particular result.</p>	<p>1.4. Ciascuna Parte si impegna a esercitare le rispettive responsabilità (i) come stabilito nel Protocollo, come modificato e approvato da tutti i comitati etici di ricerca applicabili, e (ii) in conformità a tutte le leggi, normative governative e linee guida applicabili, tra cui, in via non limitativa, le linee guida consolidate armonizzate di buona pratica clinica della conferenza internazionale sull'armonizzazione (linee guida ICH/GCP), la Dichiarazione di Helsinki e in conformità alle pratiche cliniche generalmente accettate. Nessuna Parte garantisce l'ottenimento di un risultato specifico.</p>
<p>1.5. The Parties agree that the Project will not begin at Site, and each Study will not begin at Site, until the Site Investigator has received written approval from the Site’s Research Ethics Board (“REB”).</p>	<p>1.5. Le Parti concordano che il Progetto non inizierà presso il [SITE], e ogni Studio non inizierà presso il [SITE], fino a quando il Ricercatore del [SITE] non avrà ricevuto l'approvazione scritta da parte del Comitato etico di ricerca (“REB”) del [SITE].</p>
<p>1.6. If applicable to the Protocol, The Researchers shall comply with the reporting and disclosure of adverse</p>	<p>1.6. Se applicabile al Protocollo, i Ricercatori dovranno attenersi alla segnalazione e alla divulgazione degli</p>

<p>events as set out in the applicable Protocol and Study Order. Each patient who is enrolled in a Study at the Site is a “Study Participant”. Notwithstanding anything in this Agreement to the contrary, each Party shall have the right to disclose findings that could adversely affect the safety of Study Participants to the study steering committee and/or data safety monitoring board, as applicable, REBs of participating sites and appropriate regulatory authorities if they deem it necessary to protect the health of Study Participants.</p>	<p>eventi avversi come stabilito nel Protocollo e nella Richiesta di Studio applicabili. Ogni paziente inserito in uno Studio presso il [SITE] è un "Partecipante". Nonostante qualsiasi disposizione contraria contenuta nel presente Accordo, ciascuna Parte ha il diritto di divulgare i risultati che potrebbero influire negativamente sulla sicurezza dei Partecipanti al comitato direttivo dello Studio e/o al comitato per il monitoraggio della sicurezza dei dati, a seconda dei casi, ai REB dei siti partecipanti e alle autorità di regolamentazione competenti, se lo ritengono necessario per proteggere la salute dei Partecipanti.</p>
<p>2. Financial Terms</p> <p>2.1. The Project is funded by multiple sources, including grants and company funding. A “Funder” is any entity that provides funding to be flowed to the Site for Project related activities, including for any Study. If a Funder requires additional terms to be flowed to the Site hereunder, such additional terms will be added to this Agreement by way of an amendment (if it affects the Master Protocol or multiple Studies) or a Study Order.</p>	<p>2. Clausole finanziarie</p> <p>2.1. Il Progetto è finanziato da più fonti, tra cui sovvenzioni e finanziamenti aziendali. Un "Finanziatore" è qualsiasi entità che fornisce finanziamenti da far affluire al [SITE] per le attività relative al Progetto, compreso qualsiasi Studio. Se un Finanziatore richiede l'inserimento di clausole aggiuntive nel [SITE], tali clausole aggiuntive saranno aggiunte al presente Accordo mediante una modifica (se riguarda il Protocollo Generale o più studi) o una Richiesta di Studio.</p>
<p>2.2. Funding is provided to the Site through the Study Orders in accordance with their budget terms.</p>	<p>2.2. I finanziamenti vengono erogati al [SITE] attraverso le Richieste di Studio in conformità con i loro termini di bilancio preventivo.</p>
<p>2.3. The Funder is not the regulatory sponsor of the Project or any Study. Under no circumstances is the Funder to be deemed or listed in Study documents as the sponsor of the Study as that term is defined in applicable law. The Parties acknowledge and agree that no part of any funding provided under this Agreement is a prohibited payment for recommending or arranging for the referral of business or the ordering of items or services. Neither this Agreement nor any funding or value paid hereunder is contingent upon Site's</p>	<p>2.3. Il Finanziatore non è lo sponsor normativo del Progetto o di uno Studio. In nessun caso il Finanziatore deve essere considerato o menzionato nei documenti dello Studio come sponsor dello Studio, come definito dalla legge applicabile. Le Parti riconoscono e concordano che qualsiasi finanziamento fornito in conformità con il presente Accordo costituisce in nessuna parte un pagamento vietato per raccomandare o organizzare la segnalazione di attività commerciali o l'ordine delle voci o dei servizi. Né il presente Accordo né i finanziamenti o il valore corrisposto in</p>

<p>or Site Investigator's use or purchase of any Funder's products.</p>	<p>virtù dello stesso sono condizionati all'uso o all'acquisto di prodotti del Finanziatore da parte del [SITE] o del Ricercatore del [SITE].</p>
<p>2.4. The Parties acknowledge that certain Funders may be required by law to make publicly accessible information (including personal information of investigators) related to compensation, funding, gifts, payments, meals, education and other remuneration or things of benefit provided to physicians and/or other healthcare providers and members of the healthcare community. Each Party agrees that such disclosures of personal information are permitted by the Funder and, if the Funder, Institution or UHN Investigator provides a consent form for such a purpose, Site Investigator agrees to require the study personnel at Site to provide consent in such a format. Study personnel who do not consent to such uses of their personal information will not be permitted to participate in the Project or the Study.</p>	<p>2.4. Le Parti riconoscono che alcuni Finanziatori possono essere tenuti per legge a rendere accessibili al pubblico le informazioni (incluse le informazioni personali dei ricercatori) relative a indennizzi, finanziamenti, doni, pagamenti, pasti, istruzione e altri compensi o vantaggi forniti a medici e/o altri operatori sanitari e membri della comunità sanitaria. Ciascuna Parte concorda che tali divulgazioni di informazioni personali sono consentite dal Finanziatore e, se il Finanziatore, l'Istituzione o il Ricercatore dell'UHN forniscono un modulo di consenso a tale scopo, il Ricercatore del [SITE] accetta di richiedere al personale dello Studio presso il [SITE] di fornire il consenso in tale formato. Il personale dello Studio che non acconsente a tali utilizzi dei propri dati personali non potrà partecipare al Progetto o allo Studio.</p>
<p>25. The Parties each with respect to its/him/herself represent and warrant that</p> <p>25.1. It/he/she is not excluded from a governmental healthcare program and that it/he/she has all the necessary licenses or certifications to perform its/his/her obligations under this Agreement.</p> <p>25.2. it/he/she is not and has not been debarred or disqualified from participating in clinical research by Health Canada, any United States regulatory authority, or any other governmental authority, and that it/he/she will not knowingly or negligently use or involve any person or organization in connection with the Project or Study that is or has been debarred or disqualified by any regulatory</p>	<p>2.5. Le Parti, ciascuna per quanto riguarda la propria persona, dichiarano e garantiscono di:</p> <p>25.1. Non essere state escluse da un programma sanitario governativo e di essere in possesso di tutte le licenze o certificazioni necessarie per adempiere ai propri obblighi in conformità con il presente Accordo.</p> <p>25.2. Non essere attualmente e non essere state escluse o squalificate dalla partecipazione alla ricerca clinica da parte di Health Canada, di qualsiasi autorità di regolamentazione degli Stati Uniti o di qualsiasi altra autorità governativa, e di non utilizzare o coinvolgere consapevolmente o per negligenza qualsiasi persona o organizzazione in relazione al Progetto o allo Studio da cui siano o siano state escluse o squalificate da qualsiasi autorità di regolamentazione dalla</p>

<p>authority from participating in clinical research. If Site or Site Investigator becomes aware during the course of the Project or a Study that it/he/she or any person or organization used or involved in connection with the Project or any Study at the Site has become debarred or disqualified, Site or Site Investigator, as the case may be, agrees to promptly notify Institution in writing.</p>	<p>partecipazione alla ricerca clinica. Se il [SITE] o il Ricercatore del [SITE] viene a conoscenza, nel corso del Progetto o di uno Studio, che lui/lei o qualsiasi persona o organizzazione utilizzata o coinvolta in relazione al Progetto o a qualsiasi Studio presso il [SITE] è stata esclusa o squalificata, il [SITE] o lo Sperimentatore del [SITE], a seconda dei casi, si impegna a informare prontamente l'Istituzione per iscritto.</p>
<p>2.6. The Parties agree to comply with anti-corruption and anti-bribery legislation applicable to the Parties and to the Funders. The Parties agree to comply with export control legislation provided that the Party to which the legislation applies will provide clear notification to the other Parties of the requirements in advance.</p>	<p>2.6. Le Parti si impegnano a rispettare la legislazione anticorruzione e anticorruzione applicabile alle Parti e ai Finanziatori. Le Parti convengono di rispettare la legislazione sul controllo delle esportazioni, a condizione che la Parte a cui si applica la legislazione fornisca in anticipo alle altre Parti una chiara notifica dei requisiti.</p>

<p>3. The Project Platform</p> <p>3.1. The Site Investigator and Site personnel shall, through a web-based portal, submit data, documents, records and other tangible information collected or developed as a result of conducting the Protocol at the Site to the Project Platform as set out in the Master Protocol and in the Study Protocol (such submitted data excluding any medical records or source documents belonging to the Site is the “Site’s Data”). Site’s Data is de-identified at the Site prior to submission into the Project platform. Each Study will have a data set pooled from the various sites in the Study (“Study Data”) and each Study contributes its Study Data into the pooled data in the Project Platform. The pooled data housed in the Project Platform is the “Project Data”. The submission, use and access of the Study Data shall be subject to the terms and provisions set out in the applicable Protocol as approved by the REB.</p>	<p>3. La Piattaforma del progetto</p> <p>3.1. Il Ricercatore del [SITE] e il personale del [SITE] dovranno caricare sulla Piattaforma del progetto, attraverso un portale web, dati, documenti, registri e altre informazioni tangibili raccolte o sviluppate in seguito allo svolgimento del Protocollo presso il [SITE], come stabilito nel Protocollo Generale e nel Protocollo della Studio (tali dati caricati, escluse le cartelle cliniche o i documenti di origine appartenenti al [SITE], sono i "Dati del [SITE]"). I Dati del [SITE] vengono de-identificati presso il [SITE] prima del caricamento sulla Piattaforma del progetto. Ogni studio avrà una serie di dati raccolti dai vari siti dello Studio ("Dati dello Studio") e ogni Studio contribuisce con i propri Dati dello studio ai dati raccolti nella Piattaforma del Progetto. I dati raccolti nella Piattaforma del progetto sono i "Dati del progetto". La presentazione, l'utilizzo e l'accesso dei Dati dello studio saranno soggetti ai termini e alle disposizioni stabiliti nel Protocollo applicabile, come approvato dal REB.</p>
<p>3.2. Institution shall use its existing infrastructure to house the Project Data in accordance with the Master Protocol, all applicable laws and regulations, research ethics board approval, privacy laws and the consents obtained from Study Participants and the Tri-Council Policy Statement “Ethical Conduct of Research Involving Humans”. The Project Data is used for research purposes, such as identifying potential participants for other Studies (by notifying the Site Investigator of participant code/ID that is eligible for the future Study) and for REB approved secondary analysis studies.</p>	<p>3.2. L'Istituzione utilizzerà la propria infrastruttura esistente per conservare i Dati del Progetto in conformità con il Protocollo Generale, alle normative vigenti, all'approvazione del comitato etico di ricerca, alle leggi sulla privacy e ai consensi ottenuti dai Partecipanti e al Tri-Council Policy Statement "Ethical Conduct of Research Involving Humans". I Dati del Progetto vengono utilizzati per scopi di ricerca, come l'identificazione di potenziali partecipanti per altri Studi (notificando al Ricercatore del [SITE] il codice/ID del Partecipante idoneo per il futuro Studio) e per Studi di analisi secondaria approvati dal REB.</p>

<p>3.3. Access to Project Data will be restricted to approved Project study teams and approved research Studies only. If an approved research study involves access to be provided to any third party other than approved Project study teams for approved studies (such as to a Funder), any such submission and/or access to Project Data will be subject to the approval of the Institution's REB and Institution is responsible to ensure that the third party enters into an appropriate data transfer agreement that contains terms substantially similar to the privacy and security terms of this Agreement.</p>	<p>3.3. L'accesso ai Dati del Progetto sarà limitato esclusivamente ai gruppi di studio del Progetto e agli Studi di ricerca approvati. Se uno Studio di ricerca approvato prevede l'accesso a terze parti diverse dalle squadre di studio del Progetto per studi approvati (ad esempio a un Finanziatore), qualsiasi presentazione e/o accesso ai Dati del Progetto sarà soggetto all'approvazione del REB dell'Istituzione e l'Istituzione è responsabile di garantire che le terze parti stipulino un accordo di trasferimento dei dati appropriato che contenga termini sostanzialmente simili ai termini di privacy e sicurezza del presente Accordo.</p>
<p>3.4. No Party shall use or disclose any PHI (defined below), including without limitation biological materials that contain personal health information, unless the use or disclosure is in accordance with the Protocol and consent provided by the individual to whom such information belongs (or the waiver of consent approved by the REB) or as required by law.</p>	<p>3.4. Nessuna Parte potrà utilizzare o divulgare alcuna PHI (definita di seguito), inclusi, ma in via non limitativa, i materiali biologici che contengono dati sanitari personali, a meno che l'utilizzo o la divulgazione non avvengano in conformità con il Protocollo e al consenso fornito dall'individuo a cui appartengono tali dati (o alla rinuncia al consenso approvata dal REB) o come richiesto dalla legge.</p>
<p>4. Clinical Trials and Biobanking Protocols</p> <p>4.1. If a Study is an interventional clinical trial, it will be the subject of a Study Order. The intellectual property and other provisions applicable to such a Study may be amended in the Study Order.</p>	<p>4. Protocolli di sperimentazione clinica e biobanking</p> <p>4.1. Se uno Studio è una sperimentazione clinica interventistica, sarà oggetto di una Richiesta di Studio. La proprietà intellettuale e le altre disposizioni applicabili a tale Studio possono essere modificate nella Richiesta di Studio.</p>

<p>4.2. If a Study requires the collection and transfer of biological samples, the Parties shall comply with the provisions of section 6 with respect to any personal information contained within the biological samples transferred as part of the Study. Each Party understands and acknowledges that the identity of the donor of any biological samples, whether living or deceased, is and is to remain confidential. If approved for a biobanking protocol, Institution and its agents may use and process biological samples for the purposes of the REB approved biobanking Protocol and consent forms. Unless specifically approved by the Site's REB along with a plan for future research use, Institution shall not use the biological samples except for the purposes of the Study and in accordance with the REB approved Protocol and consent forms.</p>	<p>4.2. Se uno Studio richiede la raccolta e il trasferimento di campioni biologici, le Parti si conformano alle disposizioni della sezione 6 per quanto riguarda i dati personali contenuti nei campioni biologici trasferiti nell'ambito dello Studio. Ciascuna Parte comprende e riconosce che l'identità del donatore di qualsiasi campione biologico, sia esso vivente o deceduto, è e deve rimanere riservata. Se approvato per un Protocollo di biobanking, l'Istituzione e i suoi agenti possono utilizzare ed elaborare i campioni biologici ai fini del Protocollo di biobanking approvato dal REB e dei moduli di consenso. A meno che non sia specificamente approvato dal REB del [SITE], insieme a un piano per l'utilizzo futuro della ricerca, l'istituzione non utilizzerà i campioni biologici se non per gli scopi dello Studio e in conformità con il Protocollo e i moduli di consenso approvati dal REB.</p>
<p>5. Intellectual Property and Data Ownership</p> <p>5.1. Site and Institution shall jointly own the Site's Data provided that each shall not require the approval of the other to use such Site's Data. Site retains ownership of its medical records and source documents. Study Data is owned by the Institution unless a Study Order specifies otherwise. Project Data is owned by the Institution. Subject to compliance with this Agreement, Institution shall not be required to seek approvals from Site with respect to the functioning of the Project platform or any study not being conducted at the Site.</p> <p>5.2. Unless otherwise specified in a Study Order, Institution and Site shall jointly</p>	<p>5. Proprietà intellettuale e proprietà dei dati</p> <p>5.1. Il [SITE] e l'Istituzione saranno proprietari congiuntamente dei Dati del [SITE], a condizione che ciascuno di essi non richieda l'approvazione dell'altro per utilizzare tali Dati. Il [SITE] conserva la proprietà delle cartelle cliniche e dei documenti originari. I Dati dello studio sono di proprietà dell'Istituzione, salvo diversa indicazione da parte di una Richiesta di Studio. I Dati del Progetto sono di proprietà dell'Istituzione. Fermo restando il rispetto del presente Accordo, l'Istituzione non è tenuta a richiedere al [SITE] le approvazioni relative al funzionamento della piattaforma del Progetto o a qualsiasi Studio non condotto presso il [SITE].</p> <p>5.2. Se non diversamente specificato in una Richiesta di Studio, l'Istituzione e il</p>

<p>own all inventions, discoveries, new uses, improvements, processes and/or compounds developed by the Researchers that arise directly from conduct of a Study Protocol (“Intellectual Property”) and all analyzed information, conclusions and results developed by the Researchers in the conduct of the Project and any Study (“Results”). Intellectual Property that does not fall under a Study Protocol but arises from the Project will be owned by Institution or otherwise governed by the Project’s policies.</p>	<p>[SITE] saranno proprietari congiuntamente di tutte le invenzioni, le scoperte, i nuovi usi, i miglioramenti, i processi e/o i composti sviluppati dai Ricercatori che derivano direttamente dalla conduzione di un Protocollo dello Studio (“Proprietà intellettuale”) e di tutte le informazioni analizzate, le conclusioni e i risultati sviluppati dai Ricercatori nella conduzione del Progetto e di qualsiasi Studio (“Risultati”). La Proprietà intellettuale che non rientra in un Protocollo dello Studio ma che deriva dal Progetto sarà di proprietà dell'Istituzione o comunque disciplinata dalle politiche del Progetto.</p>
<p>5.3. UHN Investigator may provide Funder with certain de-identified Study Data subject to the applicable Protocol, consent forms and privacy obligations set out in this Agreement. Institution and Site hereby each grant to Funder a non-exclusive, royalty-free license to use all Intellectual Property and Study Data for its own internal research purposes.</p>	<p>5.3. Il Ricercatore dell'UHN può fornire al Finanziatore alcuni Dati dello studio de-identificati, nel rispetto del Protocollo applicabile, dei moduli di consenso e degli obblighi di privacy previsti dal presente Accordo. L'Istituzione e il [SITE] concedono al Finanziatore una licenza non esclusiva e gratuita per l'utilizzo di tutta la Proprietà intellettuale e dei Dati dello studio per i propri scopi di ricerca interna.</p>
<p>5.4. “Registry Technology” shall mean the systems and technology developed by or for Institution in connection with the storage, distribution and tracking of the Project Data, including the software, source and object code, interfaces, methods and other intellectual property relating to the structure, design, functionality, operation and framework of the Project Platform. Institution shall own the Registry Technology.</p>	<p>5.4. “Tecnologia di registro” indica i sistemi e la tecnologia sviluppati da o per l'Istituzione in relazione all'archiviazione, alla distribuzione e al tracciamento dei Dati del Progetto, inclusi il software, il codice sorgente e il codice oggetto, le interfacce, i metodi e altre proprietà intellettuali relative alla struttura, al design, alla funzionalità, al funzionamento e al quadro della Piattaforma del progetto. L'Istituzione è proprietaria della Tecnologia di Registro.</p>
<p>6. Privacy 6.1. The Parties shall comply with applicable laws and regulations regarding protection of personal information including, but not limited to, Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the</p>	<p>6. Privacy 6.1. Le Parti si conformano alle leggi e alle normative applicabili in materia di protezione dei dati personali, tra cui, ma in via non limitativa, il Regolamento (UE) 2016/679 del Parlamento europeo e del Consiglio del 27 aprile 2016 in materia di protezione delle persone fisiche con riguardo al trattamento dei dati personali, nonché alla libera</p>

<p>processing of personal data and on the free movement of such data also referred to as the General Data Protection Regulation (“GDPR”), the U.S. Health Insurance Portability and Accountability Act (“HIPAA”), Canada’s Personal Information Protection and Electronic Documents Act (“PIPEDA”), and Ontario’s Personal Health Information Protection Act (“PHIPA”) (“Privacy Laws”). The term “PHI” or “Personal Data” means any and all of the following as applicable to the Parties and their roles under this Agreement or any Study Order: (a) “protected health information” including any limited data sets as defined under HIPAA; (b) any “personal information” as defined under PIPEDA; (c) any “personal health information” as defined under PHIPA; and (d) any “personal data” as defined under GDPR.</p>	<p>circolazione di tali dati, denominato anche Regolamento generale sulla protezione dei dati (“GDPR”), la legge statunitense Health Insurance Portability and Accountability Act (“HIPAA”), la legge canadese Personal Information Protection and Electronic Documents Act (“PIPEDA”) e la legge dell’Ontario Personal Health Information Protection Act (“PHIPA”) (“Leggi sulla privacy”). Con la sigla “PHI” o l’espressione “Dati personali” si intende tutto ciò che segue, in quanto applicabile alle Parti e ai loro ruoli in conformità con il presente Accordo o con qualsiasi Richiesta di Studio: (a) "informazioni sanitarie protette", inclusi i set di dati limitati definiti dall'HIPAA; (b) "informazioni personali" definite dal PIPEDA; (c) "informazioni sanitarie personali" definite dal PHIPA; e (d) "dati personali" definiti dal GDPR.</p>
<p>6.2. The Parties shall comply with the standard contractual clauses attached as Schedule C to this Agreement as required by GDPR for the transfer of personal data to a third country.</p>	<p>6.2. Le Parti si conformeranno alle clausole contrattuali standard allegate all’Allegato C del presente Accordo, come richiesto dal GDPR per il trasferimento di dati personali in un Paese terzo.</p>
<p>6.3. If Funder is entitled to receive de-identified data or to access identifiable data for purposes specified in the Protocol such as monitoring a Study, Institution and UHN Investigator shall ensure that such Funder has agreed to terms and conditions that are as strict as those herein with respect to maintaining the privacy of such data and records. Institution and UHN Investigator shall not and shall not permit any third party to re-identify any person from the Study Data or from any biological samples provided under this Agreement.</p>	<p>6.3. Se il Finanziatore ha il diritto di ricevere dati de-identificati o di accedere a dati identificabili per scopi specificati nel Protocollo, come ad esempio il monitoraggio di uno Studio, l’Istituzione e il Ricercatore dell’UHN devono assicurarsi che tale Finanziatore abbia accettato termini e condizioni altrettanto rigorosi di quelli qui riportati per quanto riguarda il mantenimento della privacy di tali dati e cartelle cliniche. L’Istituzione e il Ricercatore dell’UHN non potranno e non dovranno permettere a terze parti di re-identificare una persona a partire dai Dati dello studio o dai campioni biologici forniti nell’ambito del presente Accordo.</p>
<p>6.4. Researchers have the option of submitting a Study for approval as set</p>	<p>6.4. I Ricercatori hanno la possibilità di sottoporre uno Studio all’approvazione</p>

<p>out in the Master Protocol. If Site and Site Investigator are granted access to Study Data or the Project Data for a Study approved by the Project's steering committee, Site and Site Investigator shall each (i) limit its use of any PHI transferred under this Agreement for purposes specified in this Agreement and in the consent provided by the applicable Study Participant (or waiver of consent and the Protocol), or as required by law; (ii) refer to the applicable information custodian any Study Participant seeking access to the Study Participant's own PHI within 10 days; (iii) dispose of the PHI in accordance with the terms of the applicable Protocol or any other written instruction from the information custodian related to retention and disposal of PHI; (v) use appropriate security safeguards to protect the PHI from unauthorized access or use; and (vi) comply with all policies of the Project as communicated to them with respect to accessing such Project Data. Without limiting their rights and responsibilities related to Site's Data, Site and Site Investigator shall not and shall not permit any third party to re-identify any person from the Study Data, Project Data or from any biological samples provided under this Agreement.</p>	<p>secondo quanto stabilito nel Protocollo Generale. Se al [SITE] e al Ricercatore del [SITE] viene concesso l'accesso ai Dati dello studio o ai Dati del Progetto per uno Studio approvato dal comitato direttivo del Progetto, il [SITE] e il Ricercatore del [SITE] dovranno (i) limitare l'uso di qualsiasi PHI trasferita previsto dal presente Accordo per gli scopi specificati di quest'ultimo e nel consenso fornito dal Partecipante applicabile (o nella rinuncia al consenso e al Protocollo), o come richiesto dalla legge; (ii) segnalare al depositario delle informazioni competente qualsiasi Partecipante che desideri accedere alle proprie PHI entro 10 giorni; (iii) eliminare le PHI in conformità ai termini del Protocollo applicabile o a qualsiasi altra istruzione scritta del depositario delle informazioni relative alla conservazione e all'eliminazione delle PHI; (v) utilizzare adeguate misure di sicurezza per proteggere le PHI da accessi o usi non autorizzati; e (vi) rispettare tutte le politiche del Progetto comunicate loro in relazione all'accesso ai Dati del progetto. Senza limitare i loro diritti e responsabilità relativi ai Dati del [SITE], il [SITE] e il Ricercatore del [SITE] non potranno e non dovranno permettere a terze parti di re-identificare una persona a partire dai Dati dello studio, Dati del Progetto o dai campioni biologici forniti nell'ambito del presente Accordo.</p>
<p>7. Confidentiality</p> <p>7.1. "Confidential Information" is defined as all proprietary, commercial and technical information related to the Study disclosed by Institution and UHN Investigator, on the one hand, and by the Researchers on the other hand, in writing, whether or not marked as confidential. Confidential Information shall include all information which could reasonably be considered confidential; however, the Parties shall endeavour to mark information as</p>	<p>7. Riservatezza</p> <p>7.1. Per "Informazioni riservate" si intendono tutte le informazioni proprietarie, commerciali e tecniche relative allo Studio divulgate dall'Istituzione e dal Ricercatore dell'UHN, da un lato, e dai Ricercatori, dall'altro, per iscritto, indipendentemente dal fatto che siano o meno contrassegnate come riservate. Le informazioni riservate includono tutte le informazioni che potrebbero ragionevolmente essere considerate riservate; tuttavia, le Parti si impegnano</p>

<p>confidential or proprietary when first disclosed and shall endeavor to identify Information furnished during discussions or oral presentations as proprietary at the time of disclosure and confirm in writing within thirty (30) days of disclosure. The Party disclosing the Confidential Information is the “Disclosing Party” and the Party receiving Confidential Information is the “Recipient”. For clarity, the Project Data and the Master Protocol are the Confidential Information of Institution regardless of whether the Site or Site Investigator has assisted in developing either. Recipient shall hold the Confidential Information in confidence, to the same extent that they hold their own information of a similar nature in confidence, and not disclose or use the Confidential Information for any purpose other than for the performance of this Agreement.</p>	<p>a contrassegnare le informazioni come riservate o proprietarie quando vengono divulgate per la prima volta e si impegnano a identificare le Informazioni fornite durante le discussioni o le presentazioni orali come proprietarie al momento della divulgazione e a confermarlo per iscritto entro trenta (30) giorni dalla divulgazione. La Parte che divulga le Informazioni riservate è la "Parte divulgatrice" e la Parte che riceve le Informazioni riservate è la "Parte ricevente". Per chiarezza, i Dati del Progetto e il Protocollo Generale sono Informazioni riservate dell'Istituzione, indipendentemente dal fatto che il [SITE] o il Ricercatore del [SITE] abbia contribuito allo sviluppo di uno dei due. La Parte ricevente si impegna a mantenere riservate le Informazioni riservate, nella stessa misura in cui mantiene riservate le proprie informazioni di natura analoga, e a non divulgare o utilizzare le Informazioni riservate per scopi diversi dall'esecuzione del presente Accordo.</p>
<p>7.2. The obligations of confidentiality shall not apply to Confidential Information that:</p>	<p>7.2. Gli obblighi di riservatezza non si applicano alle Informazioni riservate che:</p>
<p>7.2.1. can be shown by the Recipient to have been in their possession before disclosure by Disclosing Party;</p>	<p>7.2.1. la Parte ricevente può dimostrare che fossero in suo possesso prima della divulgazione da parte della Parte divulgatrice;</p>
<p>7.2.2. at time of disclosure is, or thereafter becomes, through no fault of the Recipient part of the public domain by publication or otherwise;</p>	<p>7.2.2. al momento della divulgazione sono, o diventano in seguito, di pubblico dominio tramite pubblicazione o altro, senza colpa della Parte ricevente;</p>
<p>7.2.3. is furnished to the Recipient by a third party that is not under an obligation of confidentiality to the Disclosing Party;</p>	<p>7.2.3. sono fornite alla Parte ricevente da una terza parte che non ha l'obbligo di riservatezza nei confronti della Parte divulgatrice;</p>

<p>7.2.4. is developed by the Researchers independently of the disclosure by Disclosing Party;</p>	<p>7.2.4. sono sviluppate dai ricercatori indipendentemente dalla divulgazione da parte della Parte divulgatrice;</p>
<p>7.2.5. must reasonably be disclosed to potential Study Participants during the recruitment process, and Study Participants who are or were enrolled in the Study, or any of their lawful representatives, to obtain and maintain informed consent or as the information relates to their health, safety or diagnosis;</p>	<p>7.2.5. devono essere ragionevolmente divulgate ai potenziali Partecipanti durante il processo di reclutamento e ai Partecipanti che sono o sono stati arruolati nello Studio, o a qualsiasi loro legittimo rappresentante, per ottenere e mantenere il consenso informato o in quanto le informazioni riguardano la loro salute, sicurezza o diagnosi;</p>
<p>7.2.6. must reasonably be disclosed to regulatory authorities, the REB and/or REBs of participating centers reviewing the Protocol; or,</p>	<p>7.2.6. devono essere ragionevolmente divulgate alle autorità di regolamentazione, al REB e/o ai REB dei centri partecipanti responsabili della revisione del Protocollo; oppure,</p>
<p>7.2.7. is required by statute or judicial process to be disclosed.</p>	<p>7.2.7. è necessario che vengano divulgate ai sensi di una richiesta di legge o di un procedimento giudiziario.</p>
<p>7.3. Nothing herein shall be construed as preventing the Researchers from publishing Study Data generated by them in the performance of a Study in accordance with the publication and disclosure terms in this Agreement and the applicable Study Order.</p>	<p>7.3. Nessuna disposizione del presente documento potrà essere interpretata come un impedimento alla pubblicazione da parte dei Ricercatori dei Dati dello studio da loro generati nell'esecuzione di uno Studio, conformemente alle condizioni di pubblicazione e divulgazione previste dal presente Accordo e dalla Richiesta di Studio applicabile.</p>
<p>7.4. All obligations of confidence and nonuse created under this Section 7 shall terminate (a) for the Master Protocol, five (5) years from completion or termination of this Agreement; and (b) for each Study, five (5) years from the completion or termination of the applicable Study Order. Upon written request, Recipient agrees to return all copies of Confidential Information to Disclosing Party; provided, however, that Recipient shall be entitled to retain archival copies of all Confidential Information solely to ensure compliance with their rights and obligations hereunder.</p>	<p>7.4. Tutti gli obblighi di riservatezza e di non utilizzo creati in conformità con il presente Sezione 7 cesseranno (a) per il Protocollo Generale, cinque (5) anni dopo il completamento o la risoluzione del presente Accordo; e (b) per ogni Studio, cinque (5) anni dopo il completamento o la risoluzione della Richiesta di Studio applicabile. Su richiesta scritta, la Parte ricevente si impegna a restituire tutte le copie delle Informazioni riservate alla Parte divulgatrice; a condizione, tuttavia, che la Parte ricevente abbia il diritto di conservare copie di archivio di tutte le Informazioni riservate esclusivamente per garantire il rispetto dei propri diritti</p>

	e obblighi in conformità con il presente documento.
<p>8. Publication</p> <p>8.1. The Project publication policy, as updated from time to time, will be made available to the Researchers. The Researchers retain the right to publish or present the data and results of the Study in accordance with the Project publication policy and to list Funder as supporting the Study through provision of funding and, if applicable, to list a manufacturer as supporting the Study through provision of a product for use in the Study.</p>	<p>8. Pubblicazione</p> <p>8.1. La politica di pubblicazione del Progetto, aggiornata di volta in volta, sarà messa a disposizione dei Ricercatori. I Ricercatori mantengono il diritto di pubblicare o presentare i dati e i risultati dello Studio in conformità con la politica di pubblicazione del Progetto e di menzionare il Finanziatore come sostenitore dello Studio attraverso la fornitura di finanziamenti e, ove applicabile, di menzionare un produttore come sostenitore dello Studio attraverso la fornitura di un prodotto da utilizzare nello Studio</p>
<p>8.2. The publication policy for the Project may require that Researchers provide UHN Investigator with the proposed publication or presentation for review and/or delay before the planned date of submission for publication or presentation. The review and delay period will be as set out in the publication policy or a Study Order but shall not exceed 120 days from the date of submission to the UHN Investigator. UHN Investigator shall advise Site Investigator and Site in writing if the proposed publication or presentation contains Confidential Information as defined herein that must be removed. Upon written request, Researchers shall delete such Confidential Information; provided, however, that Institution and UHN Investigator shall not request the deletion of, and Researchers shall not be required to delete, Study Data, Results or information related to research methods used in the Study.</p>	<p>8.2. La politica di pubblicazione del Progetto può richiedere che i Ricercatori forniscano al Ricercatore dell'UHN la pubblicazione o la presentazione proposta per una revisione e/o un ritardo prima della data prevista di presentazione per la pubblicazione o la presentazione. Il periodo di revisione e di ritardo sarà quello stabilito nella politica di pubblicazione o in una Richiesta di Studio, ma non deve superare i 120 giorni dalla data di presentazione al Ricercatore dell'UHN. Il Ricercatore dell'UHN informerà per iscritto il Ricercatore del [SITE] e il [SITE] se la pubblicazione o la presentazione proposta contiene Informazioni riservate, come definite nel presente documento, che devono essere rimosse. Su richiesta scritta, i Ricercatori dovranno cancellare tali Informazioni riservate; tuttavia, l'Istituzione e il Ricercatore dell'UHN non richiederanno la cancellazione dei Dati dello studio, dei Risultati o delle informazioni relative ai metodi di ricerca utilizzati nello Studio e i Ricercatori non saranno tenuti a farlo.</p>
<p>8.3. Other than with respect to Confidential Information, nothing herein is construed as granting the Institution or any Funder any editing rights of a Site Investigator's publication or presentation. If the UHN Investigator is</p>	<p>8.3. Salvo le Informazioni riservate, nulla di quanto riportato nel presente documento è da intendersi come una concessione all'Istituzione o a un Finanziatore di diritti di modifica della pubblicazione o della presentazione di un Ricercatore del</p>

<p>a co-author with the Site Investigator, they will comply with the authorship guidelines of icmje.org. The final analysis and interpretation of the Study Data generated at the Site in the performance of this Study remains with the Site Investigator.</p>	<p>[SITE]. Se il Ricercatore dell'UHN è coautore con il Ricercatore del [SITE], si atterrà alle linee guida sulla proprietà intellettuale di icmje.org. L'analisi e l'interpretazione finale dei Dati dello studio generati presso il [SITE] nell'ambito dell'esecuzione del presente Studio spetta al Ricercatore del [SITE].</p>
<p>9. Limitation of Liability</p> <p>9.1. Each Party makes no covenants, representations or warranties, express or implied, as to any matter whatsoever, including, without limitation the Study Data, Project Data, Intellectual Property or Results, whether tangible or intangible; or the ownership, merchantability, or fitness for a particular purpose of the Study Data, Project Data, Intellectual Property or Results.</p>	<p>9. Limitazione di responsabilità</p> <p>9.1. Ciascuna Parte non conclude alcun patto, non rilascia alcuna dichiarazione o garanzia, espressa o implicita, in merito a qualsiasi questione, tra cui, ma in via non limitativa, i Dati dello studio, i Dati del progetto, la Proprietà intellettuale o i Risultati, siano essi materiali o immateriali; o la proprietà, la commerciabilità o l'idoneità per uno scopo particolare dei Dati dello studio, dei Dati del progetto, della Proprietà intellettuale o dei Risultati.</p>
<p>9.2. No Party shall be liable for any direct, indirect, consequential, or other damages suffered by another Party or any third party resulting from the use of the Study Data, Project Data, Intellectual Property or Results developed under this Agreement, except to the extent such damages arise from the Party's gross negligence or willful misconduct.</p>	<p>9.2. Nessuna Parte sarà responsabile di eventuali danni diretti, indiretti, conseguenti o di altro tipo subiti da un'altra Parte o da terze parti e derivanti dall'uso dei Dati dello studio, dei Dati del progetto, della Proprietà intellettuale o dei Risultati sviluppati nell'ambito del presente Accordo, fatto salvo nella misura in cui tali danni derivino da grave negligenza o dolo della Parte.</p>
<p>10. Indemnity</p> <p>10.1. Each Party agrees to be responsible and assume liability for his/her own negligent or intentional acts and omissions and the negligent or intentional acts and omissions of those for whom he/she is in law responsible.</p>	<p>10. Indennità</p> <p>10.1. Ciascuna Parte si impegna a essere responsabile e ad assumersi la responsabilità per i propri atti e omissioni negligenzi o intenzionali e per gli atti e le omissioni negligenzi o intenzionali di coloro per i quali è legalmente responsabile.</p>
<p>10.2. Except as a component of third party claims, no Party hereto shall be responsible for any lost profits, lost opportunities, or other indirect or consequential damages suffered by the other Party hereto as a result of the conduct of the Study or the performance of this Agreement.</p>	<p>10.2. Fatta eccezione per le richieste di terze parti, nessuna delle Parti sarà responsabile di eventuali perdite di profitto, di opportunità o di altri danni indiretti o conseguenti subiti dall'altra Parte in conseguenza dello svolgimento dello Studio o dell'esecuzione del presente Accordo.</p>

<p>10.3. Additional indemnity or liability terms for interventional clinical trial Studies may be set out in the applicable Study Order.</p>	<p>10.3. Ulteriori condizioni di indennizzo o di responsabilità per gli Studi di sperimentazione clinica interventistica possono essere stabilite nella Richiesta di Studio applicabile.</p>
<p>11. Insurance</p> <p>11.1. During the term of this Agreement and for the duration of its obligations surviving expiration or premature termination of this Agreement, each of Site and Institution shall maintain in full force and effect a policy or policies or self-insurance sufficient to cover its obligations hereunder with limits of not less than \$5,000,000.00 per occurrence/\$5,000,000.00 aggregate.</p> <p>11.2. Each of Site and Institution will provide evidence of such insurance to the other, to Site Investigator and to UHN Investigator upon written request and each will provide the other, Site Investigator and UHN Investigator with thirty (30) days prior, written notice of cancellation or non-renewal of its coverage. The minimum amounts of insurance coverage required hereunder do not create a limit of liability with respect to indemnification under this Agreement.</p>	<p>11. Assicurazione</p> <p>11.1. Per tutta la durata del presente Contratto e dei relativi obblighi che continueranno a sussistere dopo la scadenza o la risoluzione anticipata del presente Accordo, il [SITE] e l'Istituzione manterranno in vigore una o più polizze o auto assicurazioni adeguate a garantire l'adempimento dei loro obblighi in conformità con il presente Accordo con massimali non inferiori a 5.000.000,00 \$ per singolo evento e per un totale annuo aggregato di pari importo.</p> <p>11.2. Il [SITE] e l'Istituzione forniranno prova di tale assicurazione all'altra Parte, al Ricercatore del [SITE] e al Ricercatore dell'UHN su richiesta scritta. Inoltre, ciascuno si impegna a notificare per iscritto all'altra parte, al Ricercatore del [SITE] e al Ricercatore dell'UHN un preavviso di almeno trenta (30) giorni in caso di cancellazione o mancato rinnovo della copertura. I massimali minimi di copertura assicurativa richiesti nel presente documento non costituiscono un limite di responsabilità in relazione all'indennizzo previsto dal presente Accordo.</p>
<p>12. Termination</p> <p>12.1. This Agreement is effective as of the date first set out above and expires when the Project is completed unless terminated earlier in accordance with the procedures below. Any Party may terminate this Agreement upon ninety (90) days written notice to the other Parties without cause. Termination of this Agreement shall not automatically terminate any Study Order that is in effect and such Study Orders (including the applicable terms of this Agreement) shall continue until terminated in</p>	<p>12. Risoluzione</p> <p>12.1. Il presente Accordo entra in vigore a decorrere dalla data indicata in epigrafe e rimarrà valido fino al completamento del Progetto, salvo risoluzione anticipata conformemente alle procedure di seguito indicate. Ciascuna Parte potrà risolvere il presente Accordo mediante un preavviso scritto di novanta (90) giorni alle altre Parti senza giusta causa. La risoluzione del presente Accordo non comporterà la risoluzione automatica di qualsiasi Richiesta di Studio in vigore e tali Richieste di Studio (inclusi i termini applicabili del presente Accordo)</p>

<p>accordance with their terms. Upon termination of this Agreement, the Parties shall not enter into any new Study Orders and shall cooperate reasonably to terminate the activities under the Master Protocol, subject to completion or termination of any ongoing Study Orders.</p>	<p>continueranno fino a quando non saranno risolti conformemente ai relativi termini. Alla risoluzione del presente Accordo, le Parti non stipuleranno nuove Richieste di Studio e collaboreranno ragionevolmente per terminare le attività previste dal Protocollo Generale, fatto salvo il completamento o la cessazione di eventuali Richieste di Studio in corso.</p>
<p>12.2. Study Order termination rights and procedures are subject to any modifying or additional terms set out in the applicable Study Order as such rights and procedures may be subject to the requirements of Funders. Any Party may terminate a Study Order upon written notice to all the other Parties if any other Party materially breaches the Study Order and fails to cure such breach within thirty (30) days after receipt of written notice thereof from the non-breaching Party or Parties. Institution and UHN Investigator may terminate a Study Order upon sixty (60) days written notice to the other Parties without cause. Where Study Participant safety is a concern, any Party may terminate a Study Order immediately upon written notice to the other Parties. If (a) the Protocol is not approved by the REB, (b) the Study is suspended or approval is withdrawn by the REB, or (c) where the Study required regulatory approval, such regulatory approval was lost, any Party may terminate the Study Order immediately upon written notice to the other Parties. If the Investigator is unavailable to continue a Study, the Parties may agree (i) to continue the Study with a replacement investigator, or (ii) to terminate the Study Order.</p>	<p>12.2. I diritti e le procedure di risoluzione della Richiesta di Studio sono soggetti a qualsiasi termine modificativo o aggiuntivo applicabile stabilito nella stessa, in quanto tali diritti e procedure possono essere soggetti ai requisiti dei Finanziatori. Ciascuna Parte può risolvere una Richiesta di Studio con preavviso scritto a tutte le altre Parti se una qualsiasi altra Parte viola materialmente la Richiesta di Studio e non pone rimedio a tale violazione entro trenta (30) giorni dal ricevimento della relativa comunicazione scritta da parte della o delle Parti che non hanno commesso violazioni. L'Istituzione e il Ricercatore dell'UHN possono porre fine a una Richiesta di Studio con un preavviso scritto di sessanta (60) giorni alle altre Parti, senza giusta causa. Nel caso in cui sia a rischio la sicurezza dei Partecipanti, qualsiasi Parte può porre fine a una Richiesta di Studio immediatamente dopo averne dato comunicazione scritta alle altre Parti. Se (a) il Protocollo non viene approvato dal REB, (b) lo Studio viene sospeso o il REB decide di ritirare l'approvazione, o (c) nel caso in cui lo Studio richiedesse un'approvazione regolatoria e tale approvazione sia andata persa, qualsiasi Parte può porre immediatamente fine alla Richiesta di Studio mediante comunicazione scritta alle altre Parti. Se il Ricercatore non è disponibile a continuare uno Studio, le parti possono concordare (i) di continuare lo studio con un ricercatore sostitutivo o (ii) di porre fine alla Richiesta di Studio.</p>





<p>13. Procedures on Termination and Survival</p> <p>13.1. Unless other procedures related to payment upon termination are specified in the applicable Study Order, in the event of termination, Institution shall reimburse Site and Site Investigator for any and all expenses and non-cancellable obligations set out in the applicable Study Order budget properly incurred up to and including the date of termination thereof.</p>	<p>1. Procedura di risoluzione e sopravvivenza</p> <p>13.1. A meno che nell'Ordine di studio applicabile non siano specificate altre procedure relative al pagamento al momento della risoluzione, in caso di risoluzione, l'Istituzione rimborserà al Sito e al Ricercatore del sito tutte le spese e gli obblighi non annullabili indicati nel bilancio preventivo dell'Ordine di studio applicabile e adeguatamente sostenuti fino alla data di risoluzione dello stesso.</p>
<p>13.2. Termination of this Agreement or of any Study Order shall not relieve any Party of any obligation accrued prior thereto.</p>	<p>13.2. La risoluzione del presente Accordo o di qualsiasi Richiesta di Studio non solleva alcuna Parte da alcun obbligo maturato prima di esso.</p>
<p>13.3. The terms of this Agreement that require performance after expiry or termination remain in force notwithstanding expiry or other termination of this Agreement or any Study Order (with respect to such Study Order); Specifically, the following sections will survive expiry or termination of this Agreement: 3, 5-11, and 13-23.</p>	<p>13.3. I termini del presente Accordo che richiedono l'adempimento successivamente alla scadenza o alla risoluzione rimangono in vigore nonostante la scadenza o altra risoluzione del presente Accordo o di qualsiasi Richiesta di Studio (in relazione a tale Richiesta di Studio); in particolare, le seguenti sezioni sussisteranno anche dopo la scadenza o la risoluzione del presente Accordo: sezioni 3, 5-11 e 13-23.</p>
<p>14. Use of Name</p> <p>14.1. Notwithstanding anything in this Agreement to the contrary and without further notice, the Parties hereto acknowledge and agree that each of the Parties may disclose the existence of this Agreement, the title of the Protocol, identify the Parties to this Agreement, identify the Funder and disclose the amount of funding actually received pursuant to a Study Order or this Agreement, including but not limited to acknowledgment in Site's annual report or in any publication or presentation relating to the results of the Study as provided herein; and that the Site Investigator and sub-investigators may disclose the same information in a</p>	<p>14. Uso del nome</p> <p>14.1. Nonostante qualsiasi disposizione contraria contenuta nel presente Accordo e senza ulteriori avvisi, le Parti riconoscono e concordano che ciascuna di esse può divulgare l'esistenza del presente Accordo, il titolo del Protocollo, identificare le Parti del presente Accordo, identificare il Finanziatore e divulgare l'importo del finanziamento effettivo, ricevuto in conformità con una Richiesta di Studio o con il presente Accordo, incluso, ma in via non limitativa, il riconoscimento nella relazione annuale del [SITE] o in qualsiasi pubblicazione o presentazione relativa ai risultati dello Studio come previsto nel presente documento; e che il Ricercatore del [SITE] e i ricercatori</p>

<p><i>curriculum vitae</i>. However, no Party shall use the name of the other Parties in any publication, news release, promotion, advertisement, or other public announcement, whether written or oral, that endorses services, organizations or products, without the prior written approval of the Party whose name is to be used. Institution shall not permit any Funder to use the name of the Parties for any endorsement or advertising purposes.</p>	<p>subordinati possono divulgare le stesse informazioni in un curriculum vitae. Tuttavia, nessuna Parte potrà utilizzare il nome delle altre Parti in pubblicazioni, comunicati stampa, promozioni, pubblicità o altri annunci pubblici, sia scritti che orali, che approvino servizi, organizzazioni o prodotti, senza la previa approvazione scritta della Parte il cui nome deve essere utilizzato. L'Istituzione non consentirà ad alcun Finanziatore di utilizzare il nome delle Parti per scopi di sponsorizzazione o pubblicitari.</p>
<p>15. Dispute Resolution</p> <p>15.1. The Parties shall attempt in good faith to resolve any dispute arising out of or relating to this Agreement promptly by negotiation between officials or representatives who have authority to settle the controversy and who are at a higher level of management or responsibility than the persons with direct responsibility for administration of this contract.</p>	<p>15. Risoluzione delle controversie</p> <p>15.1. Le Parti cercheranno in buona fede di risolvere tempestivamente qualsiasi controversia derivante da o relativa al presente Accordo mediante negoziazione tra funzionari o rappresentanti che abbiano l'autorità di risolvere la controversia e che si trovino a un livello di gestione o responsabilità superiore a quello delle persone direttamente responsabili dell'amministrazione del presente contratto.</p>
<p>16. Governing Law</p> <p>16.1. This Agreement shall be governed by and construed in accordance with the laws of the jurisdiction of the defending Party. Each of the Parties agrees irrevocably to attorn to the exclusive jurisdiction of the courts in the defending Party's jurisdiction.</p>	<p>16. Legge applicabile</p> <p>16.1. Il presente Accordo sarà disciplinato e interpretato in conformità alle leggi della giurisdizione della Parte convenuta. Ciascuna delle Parti si impegna irrevocabilmente ad accettare la giurisdizione esclusiva dei tribunali della giurisdizione della Parte convenuta.</p>
<p>17. Entire Agreement</p> <p>17.1. The schedule(s) attached to this Agreement constitute a part of the Agreement and are binding upon the Parties. This Agreement sets forth the entire understanding between the Parties and supersedes all other understandings, whether written or oral, between any of the Parties with respect to the same subject matter, including any confidential disclosure Agreement entered into between any of the Parties and related to the Protocol. No modifications to this Agreement are</p>	<p>17. Accordo intero</p> <p>17.1. Gli allegati al presente Accordo costituiscono parte integrante dell'Accordo stesso e sono vincolanti per le Parti. Il presente Accordo rappresenta l'intera intesa tra le Parti e sostituisce qualsiasi altra intesa o negoziazione precedente, sia scritta che orale, intervenuta tra le Parti in merito allo stesso argomento, incluso eventuali accordi di divulgazione riservato, stipulato tra le Parti e relativo al Protocollo. Nessuna modifica al presente Accordo è vincolante se non viene eseguita per iscritto dalle Parti.</p>

binding unless executed in writing by the Parties hereto.			
17.2. In the event terms of this Agreement and the terms of the Protocol or any other document concerning the Study conflict, the terms of this Agreement shall govern and apply. If the terms of a Study Order and the terms of this Agreement conflict, the Study Order shall prevail with respect to that Study.		17.2. In caso di conflitto tra i termini del presente Accordo e quelli del Protocollo o di qualsiasi altro documento relativo allo Studio, prevarranno e troveranno applicazione i termini del presente Accordo. In caso di conflitto tra i termini di una Richiesta di Studio e i termini del presente Accordo, prevarrà la Richiesta di Studio in relazione a tale Studio.	
18. Notices 18.1. Any notice required or permitted to be given hereunder shall be in writing and addressed as follows:		18. Comunicazioni 18.1. Qualsiasi comunicazione, richiesta o consentita, in conformità con il presente documento dovrà essere effettuata per iscritto e indirizzata come segue:	
UHN Investigator: Dr. Ewan Goligher University Health Network Toronto General Hospital 585 University Avenue, 9-MaRS-9024 Toronto, ON M5G 2N2 Tel: (416) 340-4800 ext. 6810 E-mail: Ewan.Goligher@uhn.ca	Site: Prof.Andrea Cortegiani UOC di Anestesia e Rianimazione AOUP Paolo Giaccone Via Del Vespro 129 90127 Palermo - Sicilia Italia Tel. 390916552751 E-mail andrea.cortegiani@unipa.it	Ricercatore dell'UHN: Dr. Ewan Goligher University Health Network Toronto General Hospital 585 University Avenue, 9-MaRS-9024 Toronto, ON M5G 2N2 Tel: (416) 340-4800 est. 6810 E-mail: Ewan.Goligher@uhn.ca	Site: Prof.Andrea Cortegiani UOC di Anestesia e Rianimazione AOUP Paolo Giaccone Via Del Vespro 129 90127 Palermo - Sicilia Italia Tel. 390916552751 E-mail andrea.cortegiani@unipa.it

<p>Institution: University Health Network Eleana Rodriguez Director Research Legal - Clinical Trial Agreements University Health Network 700 University Avenue 4-131, 4th floor Toronto, ON M5G 1Z5 Tel: 647-336-9027 Email: Eleana.Rodriguez@uhn.ca</p>	<p>Azienda Ospedaliera Universitaria Policlinico Paolo Giaccone Via Del Vespro 129 90127 Palermo – Italy e-mail: convenzioni.sperimentazioni@policlinico.pa.it</p>	<p>Istituzione: University Health Network Eleana Rodriguez Direttore Legale della Ricerca - Accordi di sperimentazione clinica University Health Network 700 University Avenue 4-131, 4° piano Toronto, ON M5G 1Z5 Tel: 647-336-9027 E-mail: Eleana.Rodriguez@uhn.ca</p>	<p>Azienda Ospedaliera Universitaria Policlinico Paolo Giaccone Via Del Vespro 129 90127 Palermo – Italia e-mail: convenzioni.sperimentazioni@policlinico.pa.it</p>
<p>Notices are deemed to have been received on the day following the sending when personally delivered or sent by email, fax or other electronic communication. Notices are deemed to have been received on the second day following the sending when delivered by private courier. Notices are deemed to have been received on the fifth day following the sending when delivered by mail. Each Party may change its address for notice in writing to the other Party.</p>		<p>Le comunicazioni si considerano ricevute il giorno successivo all'invio se consegnate personalmente o inviate via e-mail, fax o altra comunicazione elettronica. Le comunicazioni si considerano ricevute il secondo giorno successivo all'invio se consegnate da un corriere privato. Le comunicazioni si considerano ricevute il quinto giorno successivo all'invio se consegnate per posta. Ciascuna Parte può modificare il proprio indirizzo per le comunicazioni segnalandolo per iscritto all'altra Parte.</p>	
<p>19. Relationship of the Parties 19.1. The Parties are independent contractors. Nothing contained herein creates between the Parties a partnership or joint venture or employment relationship. No Party has the authority to act on behalf of any other Party, or to commit any other Party in any manner or cause whatsoever or to use any other Party's name in any way not specifically authorized by this Agreement.</p>	<p>19. Rapporto tra le Parti 19.1. Le Parti agiscono in qualità di contraenti indipendenti. Nulla di quanto previsto nel presente Accordo deve essere interpretato come costitutivo di un'associazione, una joint venture, società o un rapporto di lavoro. Nessuna Parte ha l'autorità di agire in nome e per conto di un'altra Parte, né di vincolarla in alcuno modo, né di utilizzare il suo nome, fatto salvo quanto espressamente autorizzato dal presente Accordo.</p>		
<p>20. Waiver 20.1. No consent or waiver, express or implied, to or of any breach or default in the performance of any covenant or obligation hereunder constitutes a</p>	<p>20. Rinuncia 20.1. Nessun consenso o rinuncia, esplicita o implicita, rispetto a qualsiasi violazione o inadempimento di qualsiasi patto od obbligo qui previsto nel presente Accordo</p>		

<p>consent or waiver to or of any other breach or default in the performance of the same or of any other obligation hereunder. No exercise of a specific right or remedy by any Party precludes it from or prejudices it in exercising another right or pursuing another remedy or maintaining an action to which it may otherwise be entitled either at law or in equity.</p>	<p>costituirà un consenso o una rinuncia rispetto a qualsiasi altra violazione o inadempimento dello stesso o di altro obbligo qui previsto. L'esercizio di uno specifico diritto o rimedio da parte di una Parte non preclude né pregiudica l'esercizio di qualsiasi altro diritto o rimedio, né pregiudica la possibilità di intraprendere un'azione cui essa abbia altrimenti diritto in base alla legge o all'equità.</p>
<p>21. Force Majeure 21.1. No Party is liable to any other Party for any failure to perform, or delay in the performance of, any obligation under this Agreement caused by circumstances beyond its reasonable control, including but not limited to: acts of God, fire, labour difficulties, illness outbreak, pandemic, war, or governmental action. It is agreed that the time for performance shall be extended by the period of such uncontrollable circumstances.</p>	<p>21. Forza maggiore 21.1. Nessuna Parte sarà ritenuta responsabile nei confronti di un'altra Parte per l'eventuale mancata esecuzione o ritardo nell'adempimento di qualsiasi obbligo previsto dal presente Accordo, causato da circostanze al di fuori del suo ragionevole controllo, tra cui, a titolo esemplificativo ma non esaustivo: cause di forza maggiore, incendi, difficoltà lavorative, epidemie di malattie, pandemie, guerre o azioni governative. In tal caso, si conviene che i termini di esecuzione degli obblighi saranno prorogati per un periodo equivalenti alla durata di suddette circostanze.</p>
<p>22. Severability 22.1. If any provision in this Agreement is deemed void or invalid by a court of competent jurisdiction, the remaining provisions remain in full force and effect.</p>	<p>22. Clausola di salvaguardia 22.1. Qualora una qualsiasi disposizione del presente Accordo sia dichiarata nulla o non valida da un tribunale della giurisdizione competente, le restanti disposizioni resteranno in vigore a tutti gli effetti.</p>
<p>23. Assignment 23.1. No part of this Agreement may be assigned, delegated or subcontracted by any Party to any other person or third party without the prior written approval of the other Parties.</p>	<p>23. Cessione 23.1. Nessuna parte del presente Accordo potrà cedere, delegare o subappaltare, in tutto o in parte, i propri diritti o obblighi derivanti dal presente Accordo a terzi, senza il previo consenso scritto delle altre Parti.</p>
<p>24. Legal Advice 24.1. Each Party agrees that it has had the opportunity to seek independent legal advice with respect to this Agreement. Each Party has either sought such advice or has declined to do</p>	<p>24. Consulenza legale 24.1. Ciascuna Parte conviene di aver avuto la possibilità di richiedere una consulenza legale indipendente in relazione al presente Accordo. Ciascuna Parte ha richiesto tale consulenza o ha rinunciato</p>

so. Each Party is signing this Agreement voluntarily and with a full understanding of its contents.	volontariamente a tale opportunità e di sottoscrivere il presente Accordo in modo volontario e con piena consapevolezza del suo contenuto.
The Parties are signing this Agreement on the date stated in the introductory clause.	Le Parti sottoscrivono il presente Accordo alla data indicata nella clausola introduttiva.
<p>UNIVERSITY HEALTH NETWORK</p>  <p>Brad Wouters (Dec 3, 2025 16:28:11 EST) <small>12/03/2025</small></p> <hr/> <p>Name: Dr. Brad Wouters Title: Executive VP Science and Research at UHN, and Senior Scientist at Princess Margaret Cancer Centre</p>	<p>UNIVERSITY HEALTH NETWORK</p>  <p>Brad Wouters (Dec 3, 2025 16:28:11 EST) <small>12/03/2025</small></p> <hr/> <p>Nome: Dr. Brad Wouters Titolo: Vicepresidente esecutivo per la scienza e la ricerca presso l'UHN e Scienziato Senior presso il Princess Margaret Cancer Centre</p>
<p>DR. EWAN GOLIGHER</p>  <p>Ewan Goligher (Dec 3, 2025 14:00:45 EST) <small>12/03/2025</small></p> <hr/> <p>Name: Dr. Ewan Goligher Title: Clinician-Scientist and Attending Physician at Toronto General Hospital, and Associate Professor of Medicine at University of Toronto</p>	<p>DR. EWAN GOLIGHER</p>  <p>Ewan Goligher (Dec 3, 2025 14:00:45 EST) <small>12/03/2025</small></p> <hr/> <p>Nome: Dr. Ewan Goligher Titolo: Clinician-Scientist and Attending Physician at Toronto General Hospital, and Associate Professor of Medicine at University of Toronto</p>
<p>Azienda Ospedaliera Universitaria Policlinico Paolo Giaccone Dott.ssa Maria Grazia Furnari General Manager</p>	<p>Azienda Ospedaliera Universitaria Policlinico Paolo Giaccone Dott.ssa Maria Grazia Furnari Direttrice Generale</p>
<p>Azienda Ospedaliera Universitaria Policlinico Paolo Giaccone Prof. Andrea Cortegiani Researcher</p>	<p>Azienda Ospedaliera Universitaria Policlinico Paolo Giaccone Prof. Andrea Cortegiani Ricercatore</p>
<p>Schedule A Master Protocol Provided under separate cover</p>	<p>Allegato A Protocollo Generale Fornito in separata sede</p>

<p>Schedule B – Sample Study Order <i>[NTD: Please do not make changes to this sample. Terms will be updated with specifics from each Study. For countries with a national clinical trial agreement template, that template can be customized as a Study Order.]</i></p>	<p>Allegato B - Esempio di Richiesta di Studio <i>[Nota per la bozza: Non apportare modifiche a questo modello. I termini saranno aggiornati con le specifiche di ogni Studio. Per i Paesi che dispongono di un modello di accordo di sperimentazione clinica nazionale, tale modello può essere personalizzato come Richiesta di Studio.]</i></p>
<p>This Agreement is drafted in both English and Italian. The English version shall supersede the Italian version.</p>	<p>Il presente Contratto è redatto in lingua inglese e italiana. La versione in lingua inglese prevarrà su quella in lingua italiana.</p>
<p>This study order (“Study Order”) is dated [insert date] and is between [SITE], a [jurisdiction] corporation (“Site”), Dr. [NAME], an individual appointed at Site (“Site Investigator”), UNIVERSITY HEALTH NETWORK, an Ontario corporation (“Institution”) and [UHN INVESTIGATOR], an individual appointed at Institution (“UHN Investigator”). Site Investigator and Site are together referred to as “Researchers”.</p>	<p>La presente Richiesta di Studio ("Richiesta di Studio è stipulata tra [[SITE]], una società di [giurisdizione] ("[SITE]"), [RICERCATORE DEL [SITE]], una persona fisica nominata presso il [SITE] ("Ricercatore del [SITE]"), UNIVERSITY HEALTH NETWORK, una società dell'Ontario ("Istituzione") e [RICERCATORE DELL'UHN], una persona fisica nominata presso l'Istituzione ("Ricercatore dell'UHN")") in data [inserire data]. Il Ricercatore del [SITE] e il [SITE] sono indicati insieme come "Ricercatori".</p>
<p>Recitals:</p>	<p>Premessa:</p>
<p>This study order is a part of the master research agreement regarding the Practical Platform Project signed amongst the parties on [date] (“Agreement”). For the purposes of this study order, the terms “Study” and “Protocol” in the Agreement refer to the study and protocol entitled [Title]. The Protocol number is [Protocol Number].</p> <p>The Study is funded by [insert domain protocol funder] (“Funder”). The “Study Product” is [study product name] and is available at the Site or may be provided by [name of manufacturer or distributor] (“Company”) as further described in this Study Order.</p> <p>The parties wish to set out the terms under which the Site and Site Investigator will conduct the Protocol at Site and the terms under which the Site will act as a coordinating centre and country sponsor (“Country Sponsor”) for other sites in the following jurisdiction: [insert country/ies] (“Countries”).</p>	<p>La presente Richiesta di Studio è parte integrante dell'Accordo Quadro di Ricerca relativo al Progetto Practical Platform firmato tra le parti in data [data] (“Accordo”). Ai fini del presente Richiesta di Studio, i termini “Studio” e “Protocollo” nell'Accordo si riferiscono allo Studio e al Protocollo intitolati [Titolo]. Il Numero di protocollo è [Numero del protocollo].</p> <p>Lo Studio è finanziato da [inserire il finanziatore del Protocollo di riferimento] (“Finanziatore”). Il “Prodotto oggetto dello Studio” è [nome del Prodotto oggetto dello Studio] ed è disponibile presso il Centro o può essere fornito da [nome del produttore o del distributore] (“Società”) come ulteriormente descritto nella presente Richiesta di Studio.</p> <p>Le parti desiderano stabilire i termini in base ai quali il Centro e il Ricercatore del Centro condurranno il Protocollo presso il Centro e i termini in base ai quali il Centro agirà come centro di coordinamento e sponsor nazionale (“Sponsor nazionale”) per altri siti nella seguente giurisdizione: [inserire Paese/i] (“Paesi”).</p>

<p>The parties agree as follows:</p> <ol style="list-style-type: none"> 1. The Parties will conduct their respective responsibilities under the Protocol in accordance with the Agreement and the Protocol. The Site shall act as Country Sponsor and as Institution's legal representative in the Countries. [Insert additional Country Sponsor terms such as monitoring, notification of adverse events and contracting with the sites in the Countries]. 	<p>Le parti concordano quanto segue:</p> <ol style="list-style-type: none"> 1. Le Parti si assumono le rispettive responsabilità nell'ambito del Protocollo in conformità all'Accordo e al Protocollo. Il [SITE] agisce in qualità di Sponsor nazionale e di rappresentante legale dell'Istituzione nei Paesi. [Inserire ulteriori termini dello Sponsor nazionale, come il monitoraggio, la segnalazione di eventi avversi e la contrattazione con i siti nei Paesi].
<ol style="list-style-type: none"> 2. All capitalized terms have the meaning given to them in the Agreement unless stated otherwise in this Study Order. The Agreement remains in effect and this Study Order only modifies its terms as applicable to the Study mentioned herein. 	<ol style="list-style-type: none"> 2. Tutti i termini in maiuscolo hanno il significato attribuito loro nell'Accordo, salvo diversa indicazione nella presente Richiesta di Studio. L'Accordo rimane in vigore e la presente Richiesta di Studio ne modifica solo i termini in quanto applicabili allo Studio qui menzionato.
<p>3. Adverse Events/Monitoring/Regulatory Audits</p> <ol style="list-style-type: none"> a. Site and Site Investigator shall notify Institution and UHN Investigator of adverse events at the Site as set out in the Protocol. Country Sponsor is responsible for monitoring the Study. 	<p>3. Eventi avversi/Monitoraggio/Audit normativi</p> <ol style="list-style-type: none"> a. Il Centro e il Ricercatore del Centro dovranno segnalare all'Istituzione e al Ricercatore dell'UHN gli eventi avversi verificatisi nel Centro, come previsto dal Protocollo. Lo Sponsor nazionale è responsabile del monitoraggio dello Studio.
<ol style="list-style-type: none"> b. Site and Site Investigator shall notify Institution and UHN Investigator promptly upon being contacted by any regulatory authority that seeks to audit or investigate the Site's conduct of the Study or to audit the Site's operations in a manner that is related to the Study. Site and Site Investigator shall cooperate reasonably with the regulatory authority and shall, unless prohibited by law, provide Institution and UHN Investigator with copies of any correspondence with the regulatory authority and with an opportunity to attend such audits or investigations. 	<ol style="list-style-type: none"> b. Il Centro e il Ricercatore del Centro dovranno informare tempestivamente l'Istituzione e il Ricercatore dell'UHN nel caso in cui vengano contattati da qualsiasi autorità di regolamentazione che cerchi di controllare o indagare sulla conduzione dello Studio da parte del Centro o di controllare le operazioni del Centro in modo correlato allo Studio. Il Centro e il Ricercatore del Centro collaboreranno ragionevolmente con l'autorità di regolamentazione e, a meno che non sia vietato dalla legge, forniranno all'Istituzione e al Ricercatore dell'UHN copie di qualsiasi corrispondenza con l'autorità di regolamentazione e l'opportunità di partecipare a tali audit o indagini.

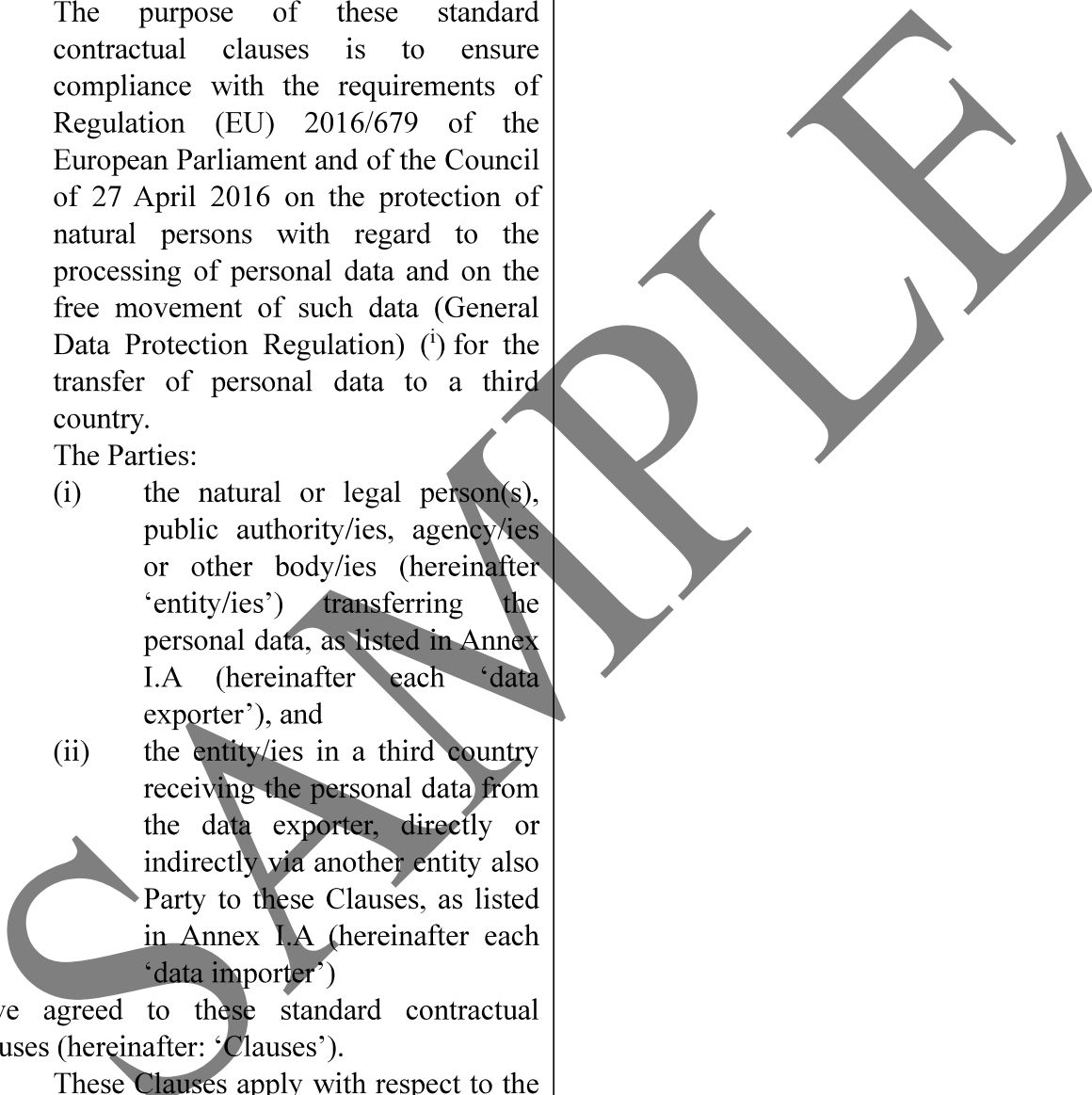
<p>4. Budget</p> <p>a. The Institution shall make payments to the Site's payee in accordance with the budget attached as Appendix B to this Study Order ("Budget").</p>	<p>4. Bilancio preventivo</p> <p>a. L'Istituzione effettuerà i pagamenti al beneficiario del Centro in conformità con il bilancio preventivo allegato come Appendice B alla presente Richiesta di Studio ("Bilancio preventivo").</p>
<p>5. Material Transfer (if applicable)</p> <p>a. [if applicable: The Researchers will use the Study Product and supplies that are available at their site. If additional product is required by the Site,] upon approval from Institution, the Researchers will be provided with such Study Product free of charge and in quantities as approved by Institution. Study Products will be shipped directly from Company to the Site. If the Study Product is provided to the Researchers hereunder, the Researchers will receive from the Company guidelines and descriptions for the safe and proper handling, use, storage and disposal of the Study Product. The Study Product is the property of Company and is being provided only for the conduct of the Study. [Subject to language negotiated with Company: Institution and Sponsor-Investigator hereby represent that in their agreement with the Company, the Company grants to Institution, Sponsor-Investigator, all participating sites and all participating investigators a non-exclusive license to use the Study Product only as outlined in this Study Order and not for any other purposes.]</p>	<p>5. Trasferimento di materiale (ove applicabile)</p> <p>a. [Ove applicabile: I ricercatori utilizzeranno il Prodotto oggetto dello Studio e le forniture disponibili presso il loro Centro. Se il Centro richiede un prodotto aggiuntivo,] previa approvazione dell'Istituzione, ai Ricercatori sarà fornito tale Prodotto oggetto dello Studio gratuitamente e nelle quantità approvate dall'Istituzione. I Prodotti di studio saranno spediti direttamente dalla Società al Centro. Se il Prodotto oggetto dello Studio viene fornito ai Ricercatori in base al presente documento, i Ricercatori riceveranno dalla Società linee guida e descrizioni per il trattamento, l'uso, la conservazione e lo smaltimento sicuro e corretto del Prodotto oggetto dello Studio. Tale Prodotto è di proprietà dell'Società e viene fornito solo per lo svolgimento dello Studio. [Soggetto a quanto negoziato con la Società: L'Istituzione e lo Sponsor-Promotore dichiarano che, nel loro accordo con la Società, quest'ultima concede all'Istituzione, allo Sponsor-Promotore, a tutti i siti partecipanti e a tutti i ricercatori partecipanti una licenza non esclusiva per l'utilizzo del Prodotto oggetto di Studio esclusivamente come indicato nella presente Richiesta di Studio e non per altri scopi.]</p>
<p>b. If Study Product is provided hereunder, unless otherwise approved by Site, under no circumstances is Site to be deemed an importer as that term is defined under applicable law.</p>	<p>b. Qualora il Prodotto oggetto di Studio è fornito in conformità con il presente documento, salvo diversa approvazione da parte del Centro, in nessun caso il Centro deve essere considerato un importatore, come tale termine è definito dalla legge applicabile.</p>

<p>c. [Subject to language negotiated with Company: Institution and Sponsor-Investigator hereby represent that in their agreement with the Company, Company makes the following representation and warranty: "Company represents and warrants to Institution, Sponsor-Investigator, all participating sites and all participating investigators that all Study Product provided hereunder shall be manufactured and provided in full compliance with all applicable government and regulatory requirements and specifications."</p>	<p>c. [Soggetto alla lingua negoziata con la Società: L'Istituzione e lo Sponsor-Promotore dichiarano che nel loro accordo con la Società, quest'ultima rilascia la seguente dichiarazione e garanzia: "La Società dichiara e garantisce all'Istituzione, allo Sponsor-Promotore, a tutti i siti partecipanti e a tutti i ricercatori partecipanti che tutti i Prodotti di studio forniti nell'ambito del presente documento saranno prodotti e forniti in piena conformità a tutti i requisiti e alle specifiche governative e normative applicabili."</p>
<p>d. Sponsor-Investigator shall provide in writing all relevant published information on all Study Products being used in the conduct of the Study and all other information necessary and sufficient to obtain informed consent from all potential Study Participants and to obtain approval from the REB. If during or after completion or termination of this Agreement information that places the safety or efficacy of the Study Product in doubt becomes available to Sponsor-Investigator, Sponsor-Investigator shall provide immediate written notice to the Researchers.</p>	<p>d. Lo Sponsor-Sperimentatore dovrà fornire per iscritto tutte le informazioni pertinenti pubblicate su tutti i Prodotti di studio utilizzati nella conduzione dello Studio e tutte le altre informazioni necessarie e sufficienti per ottenere il consenso informato da parte di tutti i potenziali Partecipanti e per ottenere l'approvazione da parte del REB. Se durante o dopo il completamento o la risoluzione del presente Accordo lo Sponsor-Promotore viene a conoscenza di informazioni che mettono in dubbio la sicurezza o l'efficacia del Prodotto oggetto dello Studio, lo Sponsor-Promotore dovrà darne immediata comunicazione scritta ai Ricercatori.</p>
<p>e. Except as otherwise stated in this Agreement, upon the direction of Sponsor-Investigator or Company [if applicable: and at Company's expense], the Researchers shall dispose of or return to Company any Study Product which is not used in the completion of the Study in accordance with clinical practices and any applicable laws or regulations.</p>	<p>e. Salvo quanto diversamente stabilito nel presente Accordo, su indicazione dello Sponsor-Promotore o della Società [ove applicabile: e a spese della Società], i Ricercatori dovranno smaltire o restituire alla Società qualsiasi Prodotto oggetto dello Studio, che non sia stato utilizzato per il completamento dello Studio in conformità alle pratiche cliniche e a qualsiasi legge o regolamento applicabile.</p>
<p>6. Confidentiality</p> <p>a. The Parties agree that any confidential information of the Funder or Company shall be considered the Confidential</p>	<p>6. Riservatezza</p> <p>a. Le Parti convengono che qualsiasi informazione riservata del Finanziatore o della Società sarà considerata</p>

<p>Information of the Institution and shall be treated in accordance with the confidentiality terms of the Agreement.</p>	<p>Informazione riservata dell'Istituzione e sarà trattata in conformità con i termini di riservatezza dell'Accordo.</p>
<p>7. Publication</p> <p>a. The publication terms in the Agreement apply to this Study [as modified by the Funder or Company additional terms set out in Appendix C].</p>	<p>7.Pubblicazione</p> <p>a. Al presente Studio si applicano i termini di pubblicazione previsti dall'Accordo [come modificati dai termini aggiuntivi del Finanziatore o della Società indicati nell'Appendice C].</p>
<p>8. Indemnity</p> <p>a. [To be inserted and customized for each Study.]</p>	<p>8. Indennità</p> <p>a. [Da inserire e personalizzare per ogni Studio.]</p>
<p>9. Termination</p> <p>a. The termination provisions of the Agreement apply to this Study Order.</p> <p>b. This Study Order is effective as of the date first set out above and expires when the Study is completed, and all payments hereunder have been made unless terminated earlier in accordance with the procedures below.</p> <p>c. In addition to the termination rights set out in the Agreement, Institution and Sponsor-Investigator may terminate this agreement at any time if their agreement with Funder or Company is terminated for any reason.</p> <p>d. In addition to the terms of the Agreement that survive the expiry or termination of this Study Order, the following sections of this Study Order will survive expiry or termination of this Study Order: sections 5(c), 5(d), 6 and 7.</p>	<p>9. Risoluzione</p> <p>a. Le disposizioni di risoluzione dell'Accordo si applicano alla presente Richiesta di Studio.</p> <p>b. La presente Richiesta di Studio ha effetto a partire dalla prima data sopra indicata e scade con il completamento dello Studio e quando tutti i pagamenti previsti dal presente documento sono stati effettuati, fatta salva risoluzione anticipata secondo le procedure indicate di seguito.</p> <p>c. Oltre ai diritti di risoluzione stabiliti nell'Accordo, l'Istituzione e lo Sponsor-Promotore possono risolvere il presente accordo in qualsiasi momento se il loro accordo con il Finanziatore o Società viene risolto per qualsiasi motivo.</p> <p>d. Oltre ai termini dell'Accordo che sopravvivono alla scadenza o alla risoluzione della presente Richiesta di Studio, le seguenti sezioni della presente Richiesta di Studio sopravvivranno alla scadenza o alla risoluzione di quest'ultima: sezioni 5(c), 5(d), 6 e 7.</p>
<p>The Parties are signing this Study Order on the date stated in the introductory clause.</p>	<p>Le Parti sottoscrivono la presente Richiesta di Studio alla data indicata nella clausola introduttiva.</p>

UNIVERSITY HEALTH NETWORK	UNIVERSITY HEALTH NETWORK
Name: Title:	Nome: Titolo:
[UHN INVESTIGATOR NAME]	[NOME DEL RICERCATORE DELL'UHN]
Name: Title:	Nome: Titolo:
[SITE NAME]	[NOME DEL [SITE]]
Name: Title:	Nome: Titolo:
[SITE INVESTIGATOR NAME]	[NOME DEL RICERCATORE DEL [SITE]]
Name: Title:	Nome: Titolo:
Appendix A Study Protocol	Appendice A Protocollo dello studio
Appendix B Study Budget	Appendice B Bilancio preventivo dello studio
Appendix C Funder or Company Additional Terms	Appendice C Termini aggiuntivi del Finanziatore o della Società

Appendix D Standard Contractual Clauses Template	Appendice D
Disclaimer: This document was generated based on the text available at https://eur-lex.europa.eu/eli/dec_impl/2021/914/oj?uri=C_ELEX%3A32021D0914&locale=en#ntc12-	

<p>L_2021199EN.01003701-E0012 and is provided for convenience purposes. It should not be considered an authoritative text or legal guidance.</p>	
<p>STANDARD CONTRACTUAL CLAUSES Controller to Controller</p>	
<p>SECTION I</p>	
<p>Clause 1 Purpose and scope</p> <p>(a) The purpose of these standard contractual clauses is to ensure compliance with the requirements of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) ⁽¹⁾ for the transfer of personal data to a third country.</p> <p>(b) The Parties:</p> <p>(i) the natural or legal person(s), public authority/ies, agency/ies or other body/ies (hereinafter ‘entity/ies’) transferring the personal data, as listed in Annex I.A (hereinafter each ‘data exporter’), and</p> <p>(ii) the entity/ies in a third country receiving the personal data from the data exporter, directly or indirectly via another entity also Party to these Clauses, as listed in Annex I.A (hereinafter each ‘data importer’)</p> <p>have agreed to these standard contractual clauses (hereinafter: ‘Clauses’).</p> <p>(c) These Clauses apply with respect to the transfer of personal data as specified in Annex I.B.</p> <p>(d) The Appendix to these Clauses containing the Annexes referred to therein forms an integral part of these Clauses.</p>	
<p>Clause 2 Effect and invariability of the Clauses</p> <p>(a) These Clauses set out appropriate safeguards, including enforceable data</p>	

<p>subject rights and effective legal remedies, pursuant to Article 46(1) and Article 46(2)(c) of Regulation (EU) 2016/679 and, with respect to data transfers from controllers to processors and/or processors to processors, standard contractual clauses pursuant to Article 28(7) of Regulation (EU) 2016/679, provided they are not modified, except to select the appropriate Module(s) or to add or update information in the Appendix. This does not prevent the Parties from including the standard contractual clauses laid down in these Clauses in a wider contract and/or to add other clauses or additional safeguards, provided that they do not contradict, directly or indirectly, these Clauses or prejudice the fundamental rights or freedoms of data subjects.</p> <p>(b) These Clauses are without prejudice to obligations to which the data exporter is subject by virtue of Regulation (EU) 2016/679</p>	
<p>Clause 3 Third-party beneficiaries</p> <p>(a) Data subjects may invoke and enforce these Clauses, as third-party beneficiaries, against the data exporter and/or data importer, with the following exceptions:</p> <ul style="list-style-type: none"> (i) Clause 1, Clause 2, Clause 3, Clause 6, Clause 7; (ii) Clause 8.5 (e) and Clause 8.9(b); (iii) N/A (iv) Clause 12(a) and (d); (v) Clause 13; (vi) Clause 15.1(c), (d) and (e); (vii) Clause 16(e); (viii) Clause 18(a) and (b). <p>(b) Paragraph (a) is without prejudice to rights of data subjects under Regulation (EU) 2016/679.</p>	
<p>Clause 4 Interpretation</p> <p>(a) Where these Clauses use terms that are defined in Regulation (EU) 2016/679,</p>	

<p>those terms shall have the same meaning as in that Regulation.</p> <p>(b) These Clauses shall be read and interpreted in the light of the provisions of Regulation (EU) 2016/679.</p> <p>(c) These Clauses shall not be interpreted in a way that conflicts with rights and obligations provided for in Regulation (EU) 2016/679.</p>	
<p>Clause 5 Hierarchy</p> <p>In the event of a contradiction between these Clauses and the provisions of related agreements between the Parties, existing at the time these Clauses are agreed or entered into thereafter, these Clauses shall prevail.</p>	
<p>Clause 6 Description of the transfer(s)</p> <p>The details of the transfer(s), and in particular the categories of personal data that are transferred and the purpose(s) for which they are transferred, are specified in Annex I.B.</p>	
<p>Clause 7 – Optional Docking clause</p> <p>(a) An entity that is not a Party to these Clauses may, with the agreement of the Parties, accede to these Clauses at any time, either as a data exporter or as a data importer, by completing the Appendix and signing Annex I.A.</p> <p>(b) Once it has completed the Appendix and signed Annex I.A, the acceding entity shall become a Party to these Clauses and have the rights and obligations of a data exporter or data importer in accordance with its designation in Annex I.A.</p> <p>(c) The acceding entity shall have no rights or obligations arising under these Clauses from the period prior to becoming a Party.</p>	
<p>SECTION II – OBLIGATIONS OF THE PARTIES</p>	
<p>Clause 8 Data protection safeguards</p> <p>The data exporter warrants that it has used reasonable efforts to determine that the data importer is able, through the implementation of</p>	

appropriate technical and organisational measures, to satisfy its obligations under these Clauses.

8.1 Purpose limitation

The data importer shall process the personal data only for the specific purpose(s) of the transfer, as set out in Annex I.B. It may only process the personal data for another purpose:

- (i) where it has obtained the data subject's prior consent;
- (ii) where necessary for the establishment, exercise or defence of legal claims in the context of specific administrative, regulatory or judicial proceedings; or
- (iii) where necessary in order to protect the vital interests of the data subject or of another natural person.

8.2 Transparency

(a) In order to enable data subjects to effectively exercise their rights pursuant to Clause 10, the data importer shall inform them, either directly or through the data exporter:

- (i) of its identity and contact details;
- (ii) of the categories of personal data processed;
- (iii) of the right to obtain a copy of these Clauses;
- (iv) where it intends to onward transfer the personal data to any third party/ies, of the recipient or categories of recipients (as appropriate with a view to providing meaningful information), the purpose of such onward transfer and the ground therefore pursuant to Clause 8.7.

(b) Paragraph (a) shall not apply where the data subject already has the information, including when such information has already been provided by the

data exporter, or providing the information proves impossible or would involve a disproportionate effort for the data importer. In the latter case, the data importer shall, to the extent possible, make the information publicly available.

(c) On request, the Parties shall make a copy of these Clauses, including the Appendix as completed by them, available to the data subject free of charge. To the extent necessary to protect business secrets or other confidential information, including personal data, the Parties may redact part of the text of the Appendix prior to sharing a copy, but shall provide a meaningful summary where the data subject would otherwise not be able to understand its content or exercise his/her rights. On request, the Parties shall provide the data subject with the reasons for the redactions, to the extent possible without revealing the redacted information.

(d) Paragraphs (a) to (c) are without prejudice to the obligations of the data exporter under Articles 13 and 14 of Regulation (EU) 2016/679.

8.3 Accuracy and data minimisation

(a) Each Party shall ensure that the personal data is accurate and, where necessary, kept up to date. The data importer shall take every reasonable step to ensure that personal data that is inaccurate, having regard to the purpose(s) of processing, is erased or rectified without delay.

(b) If one of the Parties becomes aware that the personal data it has transferred or received is inaccurate, or has become

outdated, it shall inform the other Party without undue delay.

- (c) The data importer shall ensure that the personal data is adequate, relevant and limited to what is necessary in relation to the purpose(s) of processing.

8.4 Storage limitation

The data importer shall retain the personal data for no longer than necessary for the purpose(s) for which it is processed. It shall put in place appropriate technical or organisational measures to ensure compliance with this obligation, including erasure or anonymisation⁽ⁱⁱ⁾ of the data and all back-ups at the end of the retention period.

8.5 Security of processing

- (a) The data importer and, during transmission, also the data exporter shall implement appropriate technical and organisational measures to ensure the security of the personal data, including protection against a breach of security leading to accidental or unlawful destruction, loss, alteration, unauthorised disclosure or access (hereinafter 'personal data breach'). In assessing the appropriate level of security, they shall take due account of the state of the art, the costs of implementation, the nature, scope, context and purpose(s) of processing and the risks involved in the processing for the data subject. The Parties shall in particular consider having recourse to encryption or pseudonymisation, including during transmission, where the purpose of processing can be fulfilled in that manner.
- (b) The Parties have agreed on the technical and organisational measures set out in Annex II. The

data importer shall carry out regular checks to ensure that these measures continue to provide an appropriate level of security.

(c) The data importer shall ensure that persons authorised to process the personal data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality.

(d) In the event of a personal data breach concerning personal data processed by the data importer under these Clauses, the data importer shall take appropriate measures to address the personal data breach, including measures to mitigate its possible adverse effects.

(e) In case of a personal data breach that is likely to result in a risk to the rights and freedoms of natural persons, the data importer shall without undue delay notify both the data exporter and the competent supervisory authority pursuant to Clause 13. Such notification shall contain i) a description of the nature of the breach (including, where possible, categories and approximate number of data subjects and personal data records concerned), ii) its likely consequences, iii) the measures taken or proposed to address the breach, and iv) the details of a contact point from whom more information can be obtained. To the extent it is not possible for the data importer to provide all the information at the same time, it may do so in phases without undue further delay.

(f) In case of a personal data breach that is likely to result in a high

risk to the rights and freedoms of natural persons, the data importer shall also notify without undue delay the data subjects concerned of the personal data breach and its nature, if necessary in cooperation with the data exporter, together with the information referred to in paragraph (e), points ii) to iv), unless the data importer has implemented measures to significantly reduce the risk to the rights or freedoms of natural persons, or notification would involve disproportionate efforts. In the latter case, the data importer shall instead issue a public communication or take a similar measure to inform the public of the personal data breach.

- (g) The data importer shall document all relevant facts relating to the personal data breach, including its effects and any remedial action taken, and keep a record thereof.

8.6 Sensitive data

Where the transfer involves personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, genetic data, or biometric data for the purpose of uniquely identifying a natural person, data concerning health or a person's sex life or sexual orientation, or data relating to criminal convictions or offences (hereinafter 'sensitive data'), the data importer shall apply specific restrictions and/or additional safeguards adapted to the specific nature of the data and the risks involved. This may include restricting the personnel permitted to access the personal data, additional security measures (such as pseudonymisation) and/or additional

restrictions with respect to further disclosure.

8.7 Onward transfers

The data importer shall not disclose the personal data to a third party located outside the European Union ⁽ⁱⁱⁱ⁾ (in the same country as the data importer or in another third country, hereinafter ‘onward transfer’) unless the third party is or agrees to be bound by these Clauses, under the appropriate Module. Otherwise, an onward transfer by the data importer may only take place if:

- (i) it is to a country benefitting from an adequacy decision pursuant to Article 45 of Regulation (EU) 2016/679 that covers the onward transfer;
- (ii) the third party otherwise ensures appropriate safeguards pursuant to Articles 46 or 47 of Regulation (EU) 2016/679 with respect to the processing in question;
- (iii) the third party enters into a binding instrument with the data importer ensuring the same level of data protection as under these Clauses, and the data importer provides a copy of these safeguards to the data exporter;
- (iv) it is necessary for the establishment, exercise or defence of legal claims in the context of specific administrative, regulatory or judicial proceedings;
- (v) it is necessary in order to protect the vital interests of the data subject or of another natural person; or
- (vi) where none of the other conditions apply, the data importer has obtained the explicit consent of the data subject for an onward transfer in a specific situation, after having informed him/her of its purpose(s), the identity of the recipient and the possible risks of

such transfer to him/her due to the lack of appropriate data protection safeguards. In this case, the data importer shall inform the data exporter and, at the request of the latter, shall transmit to it a copy of the information provided to the data subject.

Any onward transfer is subject to compliance by the data importer with all the other safeguards under these Clauses, in particular purpose limitation.

8.8 Processing under the authority of the data importer

The data importer shall ensure that any person acting under its authority, including a processor, processes the data only on its instructions.

8.9 Documentation and compliance

(a) Each Party shall be able to demonstrate compliance with its obligations under these Clauses. In particular, the data importer shall keep appropriate documentation of the processing activities carried out under its responsibility.

(b) The data importer shall make such documentation available to the competent supervisory authority on request.

**Clause 9
Use of sub-processors**

N/A

**Clause 10
Data subject rights**

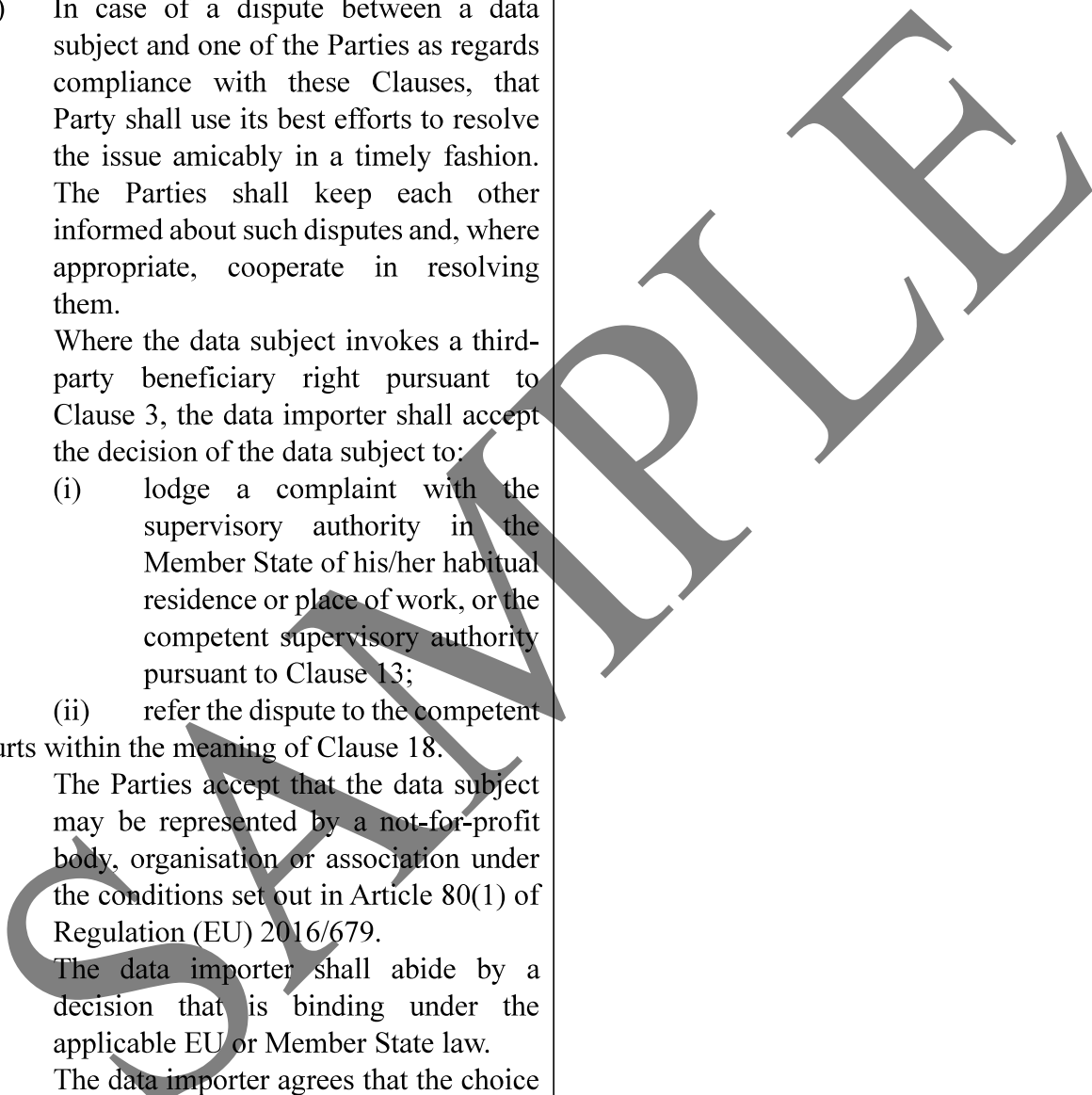
(a) The data importer, where relevant with the assistance of the data exporter, shall deal with any enquiries and requests it receives from a data subject relating to the processing of his/her personal data and the exercise of his/her rights under these Clauses without undue delay and at the latest within one month of the receipt of the enquiry or request. ^(iv) The data importer shall take appropriate measures to facilitate such enquiries, requests and the exercise of data subject rights. Any

information provided to the data subject shall be in an intelligible and easily accessible form, using clear and plain language.

(b) In particular, upon request by the data subject the data importer shall, free of charge:

- (i) provide confirmation to the data subject as to whether personal data concerning him/her is being processed and, where this is the case, a copy of the data relating to him/her and the information in Annex I; if personal data has been or will be onward transferred, provide information on recipients or categories of recipients (as appropriate with a view to providing meaningful information) to which the personal data has been or will be onward transferred, the purpose of such onward transfers and their ground pursuant to Clause 8.7; and provide information on the right to lodge a complaint with a supervisory authority in accordance with Clause 12(c)(i);
 - (ii) rectify inaccurate or incomplete data concerning the data subject;
 - (iii) erase personal data concerning the data subject if such data is being or has been processed in violation of any of these Clauses ensuring third-party beneficiary rights, or if the data subject withdraws the consent on which the processing is based.
- (c) Where the data importer processes the personal data for direct marketing purposes, it shall cease processing for such purposes if the data subject objects to it.
- (d) The data importer shall not make a decision based solely on the automated processing of the personal data transferred (hereinafter 'automated decision'), which would produce legal effects concerning the data subject or similarly significantly affect him/her,

<p>unless with the explicit consent of the data subject or if authorised to do so under the laws of the country of destination, provided that such laws lays down suitable measures to safeguard the data subject's rights and legitimate interests. In this case, the data importer shall, where necessary in cooperation with the data exporter:</p> <ul style="list-style-type: none">(i) inform the data subject about the envisaged automated decision, the envisaged consequences and the logic involved; and(ii) implement suitable safeguards, at least by enabling the data subject to contest the decision, express his/her point of view and obtain review by a human being. <p>(e) Where requests from a data subject are excessive, in particular because of their repetitive character, the data importer may either charge a reasonable fee taking into account the administrative costs of granting the request or refuse to act on the request.</p> <p>(f) The data importer may refuse a data subject's request if such refusal is allowed under the laws of the country of destination and is necessary and proportionate in a democratic society to protect one of the objectives listed in Article 23(1) of Regulation (EU) 2016/679.</p> <p>(g) If the data importer intends to refuse a data subject's request, it shall inform the data subject of the reasons for the refusal and the possibility of lodging a complaint with the competent supervisory authority and/or seeking judicial redress.</p>	
<p>Clause 11 Redress</p> <p>(a) The data importer shall inform data subjects in a transparent and easily accessible format, through individual notice or on its website, of a contact point authorised to handle complaints. It shall deal promptly with any complaints it receives from a data subject.</p>	

<p>[OPTION: The data importer agrees that data subjects may also lodge a complaint with an independent dispute resolution body (v) at no cost to the data subject. It shall inform the data subjects, in the manner set out in paragraph (a), of such redress mechanism and that they are not required to use it, or follow a particular sequence in seeking redress.]</p> <p>(b) In case of a dispute between a data subject and one of the Parties as regards compliance with these Clauses, that Party shall use its best efforts to resolve the issue amicably in a timely fashion. The Parties shall keep each other informed about such disputes and, where appropriate, cooperate in resolving them.</p> <p>(c) Where the data subject invokes a third-party beneficiary right pursuant to Clause 3, the data importer shall accept the decision of the data subject to:</p> <p>(i) lodge a complaint with the supervisory authority in the Member State of his/her habitual residence or place of work, or the competent supervisory authority pursuant to Clause 13;</p> <p>(ii) refer the dispute to the competent courts within the meaning of Clause 18.</p> <p>(d) The Parties accept that the data subject may be represented by a not-for-profit body, organisation or association under the conditions set out in Article 80(1) of Regulation (EU) 2016/679.</p> <p>(e) The data importer shall abide by a decision that is binding under the applicable EU or Member State law.</p> <p>(f) The data importer agrees that the choice made by the data subject will not prejudice his/her substantive and procedural rights to seek remedies in accordance with applicable laws.</p>	
<p>Clause 12 Liability</p> <p>(a) Each Party shall be liable to the other Party/ies for any damages it causes the other Party/ies by any breach of these Clauses.</p>	

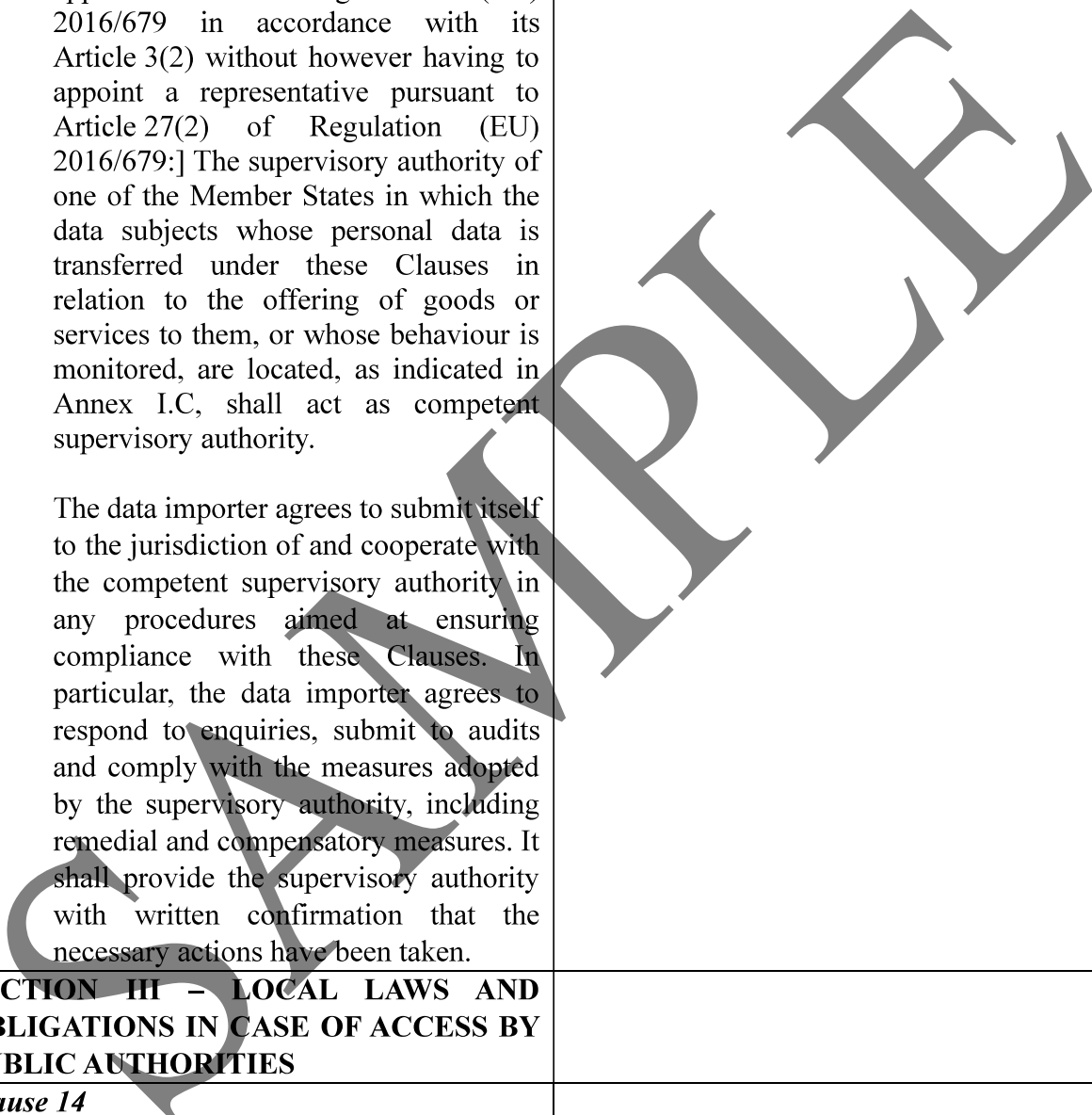
- (b) Each Party shall be liable to the data subject, and the data subject shall be entitled to receive compensation, for any material or non-material damages that the Party causes the data subject by breaching the third-party beneficiary rights under these Clauses. This is without prejudice to the liability of the data exporter under Regulation (EU) 2016/679.
- (c) Where more than one Party is responsible for any damage caused to the data subject as a result of a breach of these Clauses, all responsible Parties shall be jointly and severally liable and the data subject is entitled to bring an action in court against any of these Parties.
- (d) The Parties agree that if one Party is held liable under paragraph (c), it shall be entitled to claim back from the other Party/ies that part of the compensation corresponding to its/their responsibility for the damage.
- (e) The data importer may not invoke the conduct of a processor or sub-processor to avoid its own liability.

Clause 13

Supervision

- (a) [Where the data exporter is established in an EU Member State:] The supervisory authority with responsibility for ensuring compliance by the data exporter with Regulation (EU) 2016/679 as regards the data transfer, as indicated in Annex I.C, shall act as competent supervisory authority.

[Where the data exporter is not established in an EU Member State, but falls within the territorial scope of application of Regulation (EU) 2016/679 in accordance with its Article 3(2) and has appointed a representative pursuant to Article 27(1) of Regulation (EU) 2016/679:] The supervisory authority of the Member State in which the representative within

<p>the meaning of Article 27(1) of Regulation (EU) 2016/679 is established, as indicated in Annex I.C, shall act as competent supervisory authority.</p> <p>[Where the data exporter is not established in an EU Member State, but falls within the territorial scope of application of Regulation (EU) 2016/679 in accordance with its Article 3(2) without however having to appoint a representative pursuant to Article 27(2) of Regulation (EU) 2016/679:] The supervisory authority of one of the Member States in which the data subjects whose personal data is transferred under these Clauses in relation to the offering of goods or services to them, or whose behaviour is monitored, are located, as indicated in Annex I.C, shall act as competent supervisory authority.</p> <p>(b) The data importer agrees to submit itself to the jurisdiction of and cooperate with the competent supervisory authority in any procedures aimed at ensuring compliance with these Clauses. In particular, the data importer agrees to respond to enquiries, submit to audits and comply with the measures adopted by the supervisory authority, including remedial and compensatory measures. It shall provide the supervisory authority with written confirmation that the necessary actions have been taken.</p>	
<p>SECTION III – LOCAL LAWS AND OBLIGATIONS IN CASE OF ACCESS BY PUBLIC AUTHORITIES</p>	
<p><i>Clause 14</i></p> <p>Local laws and practices affecting compliance with the Clauses</p> <p>(a) The Parties warrant that they have no reason to believe that the laws and practices in the third country of destination applicable to the processing of the personal data by the data importer, including any requirements to disclose personal data or measures authorising</p>	

access by public authorities, prevent the data importer from fulfilling its obligations under these Clauses. This is based on the understanding that laws and practices that respect the essence of the fundamental rights and freedoms and do not exceed what is necessary and proportionate in a democratic society to safeguard one of the objectives listed in Article 23(1) of Regulation (EU) 2016/679, are not in contradiction with these Clauses.

(b) The Parties declare that in providing the warranty in paragraph (a), they have taken due account in particular of the following elements:

- (i) the specific circumstances of the transfer, including the length of the processing chain, the number of actors involved and the transmission channels used; intended onward transfers; the type of recipient; the purpose of processing; the categories and format of the transferred personal data; the economic sector in which the transfer occurs; the storage location of the data transferred;
- (ii) the laws and practices of the third country of destination— including those requiring the disclosure of data to public authorities or authorising access by such authorities – relevant in light of the specific circumstances of the transfer, and the applicable limitations and safeguards ^(vi);
- (iii) any relevant contractual, technical or organisational safeguards put in place to supplement the safeguards under these Clauses, including measures applied during transmission and to the processing of the personal data in the country of destination.

(c) The data importer warrants that, in carrying out the assessment under

paragraph (b), it has made its best efforts to provide the data exporter with relevant information and agrees that it will continue to cooperate with the data exporter in ensuring compliance with these Clauses.

(d) The Parties agree to document the assessment under paragraph (b) and make it available to the competent supervisory authority on request.

(e) The data importer agrees to notify the data exporter promptly if, after having agreed to these Clauses and for the duration of the contract, it has reason to believe that it is or has become subject to laws or practices not in line with the requirements under paragraph (a), including following a change in the laws of the third country or a measure (such as a disclosure request) indicating an application of such laws in practice that is not in line with the requirements in paragraph (a).

(f) Following a notification pursuant to paragraph (e), or if the data exporter otherwise has reason to believe that the data importer can no longer fulfil its obligations under these Clauses, the data exporter shall promptly identify appropriate measures (e.g. technical or organisational measures to ensure security and confidentiality) to be adopted by the data exporter and/or data importer to address the situation. The data exporter shall suspend the data transfer if it considers that no appropriate safeguards for such transfer can be ensured, or if instructed by the competent supervisory authority to do so. In this case, the data exporter shall be entitled to terminate the contract, insofar as it concerns the processing of personal data under these Clauses. If the contract involves more than two Parties, the data exporter may exercise this right to termination only with respect to the relevant Party, unless the Parties have agreed otherwise. Where the contract is

<p>terminated pursuant to this Clause, Clause 16(d) and (e) shall apply.</p>	
<p>Clause 15 Obligations of the data importer in case of access by public authorities 15.1 Notification</p> <p>(a) The data importer agrees to notify the data exporter and, where possible, the data subject promptly (if necessary with the help of the data exporter) if it:</p> <ul style="list-style-type: none">(i) receives a legally binding request from a public authority, including judicial authorities, under the laws of the country of destination for the disclosure of personal data transferred pursuant to these Clauses; such notification shall include information about the personal data requested, the requesting authority, the legal basis for the request and the response provided; or(ii) becomes aware of any direct access by public authorities to personal data transferred pursuant to these Clauses in accordance with the laws of the country of destination; such notification shall include all information available to the importer. <p>(b) If the data importer is prohibited from notifying the data exporter and/or the data subject under the laws of the country of destination, the data importer agrees to use its best efforts to obtain a waiver of the prohibition, with a view to communicating as much information as possible, as soon as possible. The data importer</p>	

agrees to document its best efforts in order to be able to demonstrate them on request of the data exporter.

(c) Where permissible under the laws of the country of destination, the data importer agrees to provide the data exporter, at regular intervals for the duration of the contract, with as much relevant information as possible on the requests received (in particular, number of requests, type of data requested, requesting authority/ies, whether requests have been challenged and the outcome of such challenges, etc.).

(d) The data importer agrees to preserve the information pursuant to paragraphs (a) to (c) for the duration of the contract and make it available to the competent supervisory authority on request.

(e) Paragraphs (a) to (c) are without prejudice to the obligation of the data importer pursuant to Clause 14(e) and Clause 16 to inform the data exporter promptly where it is unable to comply with these Clauses.

SECTION IV – FINAL PROVISIONS

Clause 16

Non-compliance with the Clauses and termination

(a) The data importer shall promptly inform the data exporter if it is unable to comply with these Clauses, for whatever reason.

(b) In the event that the data importer is in breach of these Clauses or unable to comply with these Clauses, the data exporter shall suspend the transfer of personal data to the data importer until compliance is again ensured or the contract is terminated. This is without prejudice to Clause 14(f).

(c) The data exporter shall be entitled to terminate the contract, insofar as it concerns the processing of personal data under these Clauses, where:

- (i) the data exporter has suspended the transfer of personal data to the data importer pursuant to paragraph (b) and compliance with these Clauses is not restored within a reasonable time and in any event within one month of suspension;
- (ii) the data importer is in substantial or persistent breach of these Clauses; or
- (iii) the data importer fails to comply with a binding decision of a competent court or supervisory authority regarding its obligations under these Clauses.
- In these cases, it shall inform the competent supervisory authority of such non-compliance. Where the contract involves more than two Parties, the data exporter may exercise this right to termination only with respect to the relevant Party, unless the Parties have agreed otherwise.
- (d) Personal data that has been transferred prior to the termination of the contract pursuant to paragraph (c) shall at the choice of the data exporter immediately be returned to the data exporter or deleted in its entirety. The same shall apply to any copies of the data. The data importer shall certify the deletion of the data to the data exporter. Until the data is deleted or returned, the data importer shall continue to ensure compliance with these Clauses. In case of local laws applicable to the data importer that prohibit the return or deletion of the transferred personal data, the data importer warrants that it will continue to ensure compliance with these Clauses and will only process the data to the extent and for as long as required under that local law.
- (e) Either Party may revoke its agreement to be bound by these Clauses where (i) the European Commission adopts a decision pursuant to Article 45(3) of Regulation (EU) 2016/679 that covers the transfer of personal data to which these Clauses

<p>apply; or (ii) Regulation (EU) 2016/679 becomes part of the legal framework of the country to which the personal data is transferred. This is without prejudice to other obligations applying to the processing in question under Regulation (EU) 2016/679.</p>	
<p>Clause 17 Governing law</p> <p>These Clauses shall be governed by the law of one of the EU Member States, provided such law allows for third-party beneficiary rights. The Parties agree that this shall be the law of - _____ (<i>specify Member State</i>).</p>	
<p>Clause 18 Choice of forum and jurisdiction</p> <p>(a) Any dispute arising from these Clauses shall be resolved by the courts of an EU Member State.</p> <p>(b) The Parties agree that those shall be the courts of _____ (<i>specify Member State</i>).</p> <p>(c) A data subject may also bring legal proceedings against the data exporter and/or data importer before the courts of the Member State in which he/she has his/her habitual residence.</p> <p>(d) The Parties agree to submit themselves to the jurisdiction of such courts.</p>	

ⁱ Where the data exporter is a processor subject to Regulation (EU) 2016/679 acting on behalf of a Union institution or body as controller, reliance on these Clauses when engaging another processor (sub-processing) not subject to Regulation (EU) 2016/679 also ensures compliance with Article 29(4) of Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC ([OJL 295, 21.11.2018, p. 39](#)), to the extent these Clauses and the data protection obligations as set out in the contract or other legal act between the controller and the processor pursuant to Article 29(3) of Regulation (EU) 2018/1725 are aligned. This will in particular be the case where the controller and processor rely on the standard contractual clauses included in Decision 2021/915.

ⁱⁱ This requires rendering the data anonymous in such a way that the individual is no longer identifiable by anyone, in line with recital 26 of Regulation (EU) 2016/679, and that this process is irreversible.

ⁱⁱⁱ The Agreement on the European Economic Area (EEA Agreement) provides for the extension of the European Union's internal market to the three EEA States Iceland, Liechtenstein and Norway. The Union data protection legislation, including Regulation (EU) 2016/679, is covered by the EEA Agreement and has been incorporated into Annex XI thereto. Therefore, any disclosure by the data importer to a third party located in the EEA does not qualify as an onward transfer for the purpose of these Clauses.

^{iv} That period may be extended by a maximum of two more months, to the extent necessary taking into account the complexity and number of requests. The data importer shall duly and promptly inform the data subject of any such extension.

^v The data importer may offer independent dispute resolution through an arbitration body only if it is established in a country that has ratified the New York Convention on Enforcement of Arbitration Awards.

^{vi} As regards the impact of such laws and practices on compliance with these Clauses, different elements may be considered as part of an overall assessment. Such elements may include relevant and documented practical experience with prior instances of requests for disclosure from public authorities, or the absence of such requests, covering a sufficiently representative time-frame. This refers in particular to internal records or other documentation, drawn up on a continuous basis in accordance with due diligence and certified at senior management level, provided that this information can be lawfully shared with third parties. Where this practical experience is relied upon to conclude that the data importer will not be prevented from complying with these Clauses, it needs to be supported by other relevant, objective elements, and it is for the Parties to consider carefully whether these elements together carry sufficient weight, in terms of their reliability and representativeness, to support this conclusion. In particular, the Parties have to take into account whether their practical experience is corroborated and not contradicted by publicly available or otherwise accessible, reliable information on the existence or absence of requests within the same sector and/or the application of the law in practice, such as case law and reports by independent oversight bodies.

SAMPLE

APPENDIX

EXPLANATORY NOTE:

It must be possible to clearly distinguish the information applicable to each transfer or category of transfers and, in this regard, to determine the respective role(s) of the Parties as data exporter(s) and/or data importer(s). This does not necessarily require completing and signing separate appendices for each transfer/category of transfers and/or contractual relationship, where this transparency can be achieved through one appendix. However, where necessary to ensure sufficient clarity, separate appendices should be used.

SAMPLE

ANNEX I

A. LIST OF PARTIES

Data exporter(s): *[Identity and contact details of the data exporter(s) and, where applicable, of its/their data protection officer and/or representative in the European Union]*

Name: _____

Address: _____

Contact person's name, position and contact details: _____

Activities relevant to the data transferred under these Clauses: _____

Signature and date: _____

Data Importer
2.

A. ELENCO DELLE PARTI

Parte divulgatrice dei dati: *[Identità e dati di contatto della Parte divulgatrice o degli esportatori di dati e, ove applicabile, del suo responsabile della protezione dei dati e/o rappresentante nell'Unione europea]*

Nome: _____

Indirizzo: _____

Nome, posizione e recapiti della persona di riferimento: _____

Attività rilevanti per i dati trasferiti in conformità con le presenti Clausole: _____

Firma e data: _____

Titolare del trattamento
2.

Data importer(s): *[Identity and contact details of the data importer(s), including any contact person with responsibility for data protection]*

Name: _____

Address: _____

Contact person's name, position and contact details: _____

Activities relevant to the data transferred under these Clauses: _____

Signature and date: _____

Role (controller/processor): Controller
2. ...

Parte Ricevente di dati: *[Identità e dati di contatto della Parte ricevente o degli importatori di dati, inclusa qualsiasi persona di contatto responsabile della protezione dei dati]*

Nome: _____

Indirizzo: _____

Nome, posizione e recapiti della persona di riferimento: _____

Attività rilevanti per i dati trasferiti in conformità con le presenti Clausole: _____

Firma e data: _____

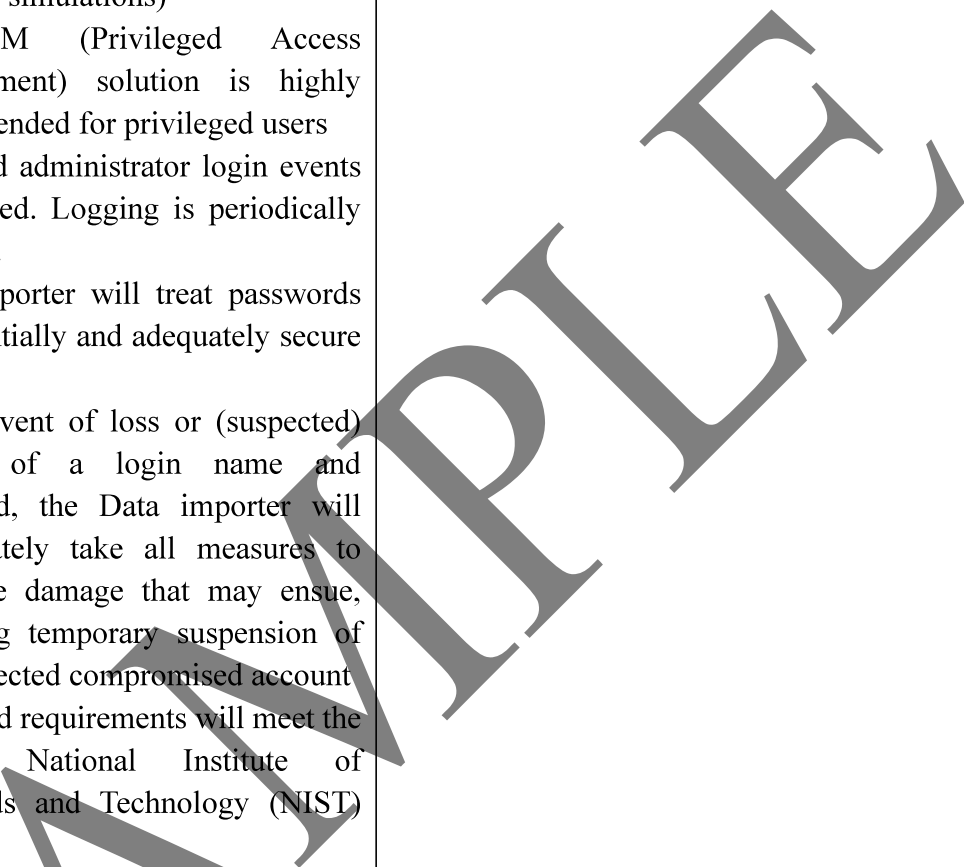
Ruolo (responsabile/titolare del trattamento):
2. ...

B. DESCRIPTION OF TRANSFER	
<i>Categories of data subjects whose personal data is transferred</i>	
<i>Categories of personal data transferred</i>	
<i>Sensitive data transferred (if applicable) and applied restrictions or safeguards that fully take into consideration the nature of the data and the risks involved, such as for instance strict purpose limitation, access restrictions (including access only for staff having followed specialised training), keeping a record of access to the data, restrictions for onward transfers or additional security measures.</i>	
<i>The frequency of the transfer (e.g. whether the data is transferred on a one-off or continuous basis).</i>	
<i>Nature of the processing</i>	
<i>Purpose(s) of the data transfer and further processing</i>	
<i>The period for which the personal data will be retained, or, if that is not possible, the criteria used to determine that period</i>	
<i>For transfers to (sub-) processors, also specify subject matter, nature and duration of the processing</i>	
C. COMPETENT SUPERVISORY AUTHORITY	
<i>Identify the competent supervisory authority/ies in accordance with Clause 13</i>	

<p style="text-align: center;">ANNEX II</p>	
<p>TECHNICAL AND ORGANISATIONAL MEASURES INCLUDING TECHNICAL AND ORGANISATIONAL MEASURES TO ENSURE THE SECURITY OF THE DATA</p>	
<p>EXPLANATORY NOTE: The technical and organisational measures must be described in specific (and not generic) terms. See also the general comment on the first page of the Appendix, in particular on the need to clearly indicate which measures apply to each transfer/set of transfers. <i>Description of the technical and organisational measures implemented by the data importer(s) (including any relevant certifications) to ensure an appropriate level of security, taking into account the nature, scope, context and purpose of the processing, and the risks for the rights and freedoms of natural persons.</i></p>	
<p>Organized by example measure (there are repeats when the item applies to more than one example):</p>	
<p><i>Measures of pseudonymisation and encryption of personal data</i></p> <ul style="list-style-type: none"> • Encryption of personal data during transmission. • Encryption methods and implementation will meet current standards that the National Institute of Standards and Technology (NIST) advises. 	
<p><i>Measures for ensuring ongoing confidentiality, integrity, availability and resilience of processing systems and services</i></p> <ul style="list-style-type: none"> • Data are transported by secure, encrypted means meeting NIST standards. • Data importer will verify and confirm receipt of data. • Physical measures for access security, including organizational control. • Access to data is only allowed for qualified persons and who have a 	

valid need to access the data (principle of least privilege).

- All end user accounts are personal. Shared accounts for accessing the data are not available.
- End user accounts are monitored, logged and reviewed regularly
- Access, where and when possible, to the data is logged.
- Multi factor authentication (> 2 factors, where a username and password counts as 2 factors) is required when accessing data outside the buildings controlled networks by the data importer.
- Measures against malicious software (anti-virus, anti-spam, EDR, etc.) on endpoints and servers are collected and monitored centrally (e.g. through a SOC/Security Operations Centre).
- Outer perimeter security is managed and monitored via Next Generation Firewalls.
- There is continuous monitoring of network traffic for suspicious behaviour.
- Change Management procedures are in place for all changes in data or in information processing or systems and services which host or transport the data
- Patch management processes are in place following an articulated standard that ensures that patches are applied in a timely manner based on their severity
- IT Administrator privileges are granted based on the principle of least privilege.
- Periodic internal audits to ensure compliance with standards and requirements, the results of which at a high level should be made available to UHN when requested.

<ul style="list-style-type: none"> • Periodic external audits are conducted to ensure compliance with standards and requirements. • There is mandatory awareness training for employees with regard to security and privacy. • Employees are measured on their cyber awareness training (e.g. via phishing simulations) • A PAM (Privileged Access Management) solution is highly recommended for privileged users • User and administrator login events are logged. Logging is periodically checked. • Data importer will treat passwords confidentially and adequately secure them. • In the event of loss or (suspected) misuse of a login name and password, the Data importer will immediately take all measures to limit the damage that may ensue, including temporary suspension of the suspected compromised account • Password requirements will meet the current National Institute of Standards and Technology (NIST) advises. 	
<p><i>Measures for ensuring the ability to restore the availability and access to personal data in a timely manner in the event of a physical or technical incident</i></p> <ul style="list-style-type: none"> • Regular system tests and logs to ensure integrity and provenance of back up data. Such data is limited to that data which may impact the agreement deliverables between UHN and the data importer 	
<p><i>Processes for regularly testing, assessing and evaluating the effectiveness of technical and organisational measures in order to ensure the security of the processing</i></p> <ul style="list-style-type: none"> • Periodic internal audits to ensure compliance with standards and 	

<p>requirements, the results of which at a high level should be made available to UHN when requested.</p> <ul style="list-style-type: none"> • Periodic external audits to ensure compliance with standards and requirements, the results of which at a high level should be made available to UHN when requested. • Measures against malicious activity (anti-virus, anti-spam, EDR, etc.) on endpoints, servers and networks are collected and monitored centrally through dashboards and periodically reviewed by senior management. Such measures and dashboards should be reasonably based on a framework such as NIST or ISO 27001 • Access, where and when possible, to the data is logged. 	
<p><i>Measures for user identification and authorisation</i></p> <ul style="list-style-type: none"> • Multi factor authentication (> 2 factors, where a username and password counts as 2 factors) is required when accessing data outside the buildings controlled networks by the data importer. • Password requirements will meet the current National Institute of Standards and Technology (NIST) advises. • Access accounts are personal. Shared accounts for accessing the data are not available. 	
<p><i>Measures for the protection of data during transmission</i></p> <ul style="list-style-type: none"> • Data are transported by secure, encrypted means meeting NIST standards. • Securing network connections via latest secure versions of SSL (Secure Socket Layer). • Data importer will verify and confirm receipt of data. 	

Measures for the protection of data during storage


- Physical security measures are in place for all data centres and core network components
- There is a data classification standard used by the importer for classifying and assigning risk to all data hosted by the importer, with corresponding controls based on risk
- Access to data is only allowed for qualified persons and who have a valid need to access the data (principle of least privilege).
- Responsibilities for the management and oversight of the imported data are assigned to one or two individuals.
- Multi factor authentication (> 2 factors, where a username and password counts as 2 factors) is required when accessing data outside the buildings controlled networks by the data importer.
- Measures against malicious software (anti-virus, anti-spam, EDR, etc.) on endpoints and servers are collected and monitored centrally (e.g. through a SOC/Security Operations Centre).
- Outer perimeter security is managed and monitored via Next Generation Firewalls.
- Monitoring of network traffic on suspicious behaviour.
- Change Management procedures are in place for all changes in data or in information processing or systems and services which host or transport the data
- Patch management processes are in place following an articulated standard that ensures that patches are applied in a timely manner based on their severity
- Access is granted based on the principle of least privilege.

- Periodic internal audits to ensure compliance with standards and requirements, the results of which at a high level should be made available to UHN when requested.
- Periodic external audits to ensure compliance with standards and requirements.
- There is mandatory awareness training for employees with regard to security and privacy.
- Employees are measured on their cyber awareness training (e.g. via phishing simulations)
- A PAM (Privileged Access Management) solution is highly recommended for privileged users
- Access, where and when possible, to the data is logged.
- Data importer will treat passwords confidentially and adequately secure them.
- Only personal accounts will be used no shared accounts.
- In the event of loss or (suspected) misuse of the login codes and passwords, Data importer will immediately take all measures to limit the damage that may ensue.
- Password requirements will meet the current National Institute of Standards and Technology (NIST) advises.

Measures for ensuring physical security of locations at which personal data are processed

- The data centres where the data will be stored have physical security controlled access
- Data centres have proper power and cooling redundancy.
- All core network components have physical access controls (locked cages/racks/rooms)
- There is an emergency notification system which ensures

<p>responsiveness to unexpected events such as power or cooling failures.</p> <ul style="list-style-type: none"> • There is video surveillance 24/7 within the buildings that host IT infrastructure and on premises security staff monitor access to the building 24/7. 	
<p><i>Measures for ensuring events logging</i></p> <ul style="list-style-type: none"> • All logs from IT services (servers, networks, storage firewall) are continuously monitored with the ability to create alerts based on thresholds that would indicate system malfunctions, compromises, or suspicious behaviour 	
<p><i>Measures for ensuring system configuration, including default configuration</i></p> <ul style="list-style-type: none"> • Change Management procedures are in place for all changes in data or in information processing or systems and services which host or transport the data • Patch management processes are in place following an articulated standard that ensures that patches are applied in a timely manner based on their severity 	
<p><i>Measures for internal IT and IT security governance and management</i></p> <ul style="list-style-type: none"> • A written established security policy including implementation which is based on a periodic risk assessment. • Security policies are periodically reviewed and adapted by senior executive management. • Data importer continuously monitors incidents, performance of the IT systems and continuously improves security, with high level oversight by senior executive management • Responsibilities for information security have been assigned. • Employee confidentiality obligations are in place and defined by policy. 	

<ul style="list-style-type: none"> • Screening of new employees occurs and includes relevant criminal background checks • Change Management procedures are in place for all changes in data or in information processing or systems and services which host or transport the data • Patch management processes are in place following an articulated standard that ensures that patches are applied in a timely manner based on their severity • Access are granted based on the principle of least privilege. • Periodic internal audits to ensure compliance with standards and requirements, the results of which at a high level should be made available to UHN when requested. • Periodic external audits to ensure compliance with standards and requirements. • There is mandatory awareness training for employees with regard to security and privacy. • Employees are measured on their cyber awareness training (e.g. via phishing simulations) • A PAM (Privileged Access Management) solution is highly recommended for privileged users • Access, where and when possible, to the data is logged. 	
<p><i>Measures for certification/assurance of processes and products</i></p> <ul style="list-style-type: none"> • Regular internal or external audits • An oversight structure is in place that manages and steers the overall direction of the cyber security program 	
<p><i>Measures for ensuring data minimisation</i></p>	
<p><i>Measures for ensuring data quality</i></p>	
<p><i>Measures for ensuring limited data retention</i></p> <ul style="list-style-type: none"> • The need for access to data is periodically checked and is defined 	

<p>as an institutional policy or standard. When access is not needed (anymore) access privileges are revoked asap.</p>	
<p><i>Measures for ensuring accountability</i></p> <ul style="list-style-type: none"> • Access, where and when possible, to the data is logged. • In the event of loss or (suspected) misuse of the login codes and passwords, Data importer will immediately take all measures to limit the damage that may ensue. • Password requirements will meet the current National Institute of Standards and Technology (NIST) advises. • The need for access to the data is periodically checked. When access is not needed (anymore) access privileges are revoked asap. • Responsibilities for the data are assigned to one or two individuals. • Data importer can demonstrate effectiveness of measures taken. 	
<p><i>Measures for allowing data portability and ensuring erasure</i></p> <ul style="list-style-type: none"> • After termination of this agreement all data, including where possible all back-ups of data, will be securely erased. • Erasure will meet the current NIST Guideline Guidelines for Media Sanitization. Data importer will confirm data destruction with a written guarantee of having accomplished as such • Any identifiable data elements are not to be published or shared outside of the definitions found in the terms of the contract between UHN and the data importer • DPA with processors. • Data importer shall not attempt in any way to identify or contact the individuals from whom such Data were collected. 	

<ul style="list-style-type: none">• Data importer shall not link the Data to other data.	
End of Sample Study Order	

SAMPLE