**LICENSE AGREEMENT**

This License Agreement (“Agreement”) is entered into as of the date of last signature (“Effective Date”) between eResearchTechnology, Inc., a Clario company, together with its subsidiaries and affiliates (“Licensor” or “ERT”), a Delaware corporation, with an address at 1818 Market Street, Suite 2600, Philadelphia, PA 19103 and ENTER YOUR COMPANY NAME (“Licensee”), a ENTER COMPANY’S STATE/COUNTRY corporation, with an address at ENTER YOUR COMPANY ADDRESS.

Preliminary Statements

WHEREAS, Licensor has the exclusive right to incorporate the Columbia-Suicide Severity Rating Scale (clinician administered version) (the “Scale” or “C-SSRS”) into any electronic format.

WHEREAS, Licensee desires to license the Scale from Licensor and create and use an electronic version of the Scale in connection with one or more specific clinical research studies or clinical research projects.

NOW THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Licensee and Licensor, desiring to be legally bound, agree as follows:

1. **DEFINITIONS.**

**1.1 Defined Terms.** Capitalized terms used in this Agreement and not otherwise defined herein shall have the meaning set forth below.

***Confidential Information*** means all data, specifications and know-how related to the Scale, as well as all other information and data provided by either party to the other party pursuant to this Agreement or any Project Notification Form (“PNF”) in written or other tangible medium, disclosed orally or displayed, except any portion thereof which: (i) is known to the receiving party, as evidenced by the receiving party’s written records, before receipt thereof under this Agreement or any PNF; (ii) is disclosed to the receiving party by a third person who is under no obligation of confidentiality to the disclosing party hereunder with respect to such information and who otherwise has a right to make such disclosure; (iii) is or becomes generally known in the trade through no fault of the receiving party; (iv) is independently developed by the receiving party, as evidenced by the receiving party’s written records, without access to such information; or (v) is the subject of a subpoena or other validly issued administrative or judicial process requesting disclosure of such Confidential Information; provided, the party that receives such order or process shall use reasonable efforts to provide prompt notice to the disclosing party and permits the disclosing party to contest or narrow such request for disclosure and thereafter complies with such subpoena or other process.

***Force Majeure*** means any event beyond the control of the parties, including, without limitation, fire, flood, riots, strikes, labor disputes, epidemics/pandemics, war (declared or undeclared and including the continuance, expansion or new outbreak of any war or conflict now in existence), terrorist acts, embargoes and governmental actions or decrees.

***Person*** means any individual, corporation, association, partnership (general or limited), joint venture, trust, estate, limited liability company, limited liability partnership, unincorporated organization, government (or any agency or political subdivision thereof) or other legal entity or organization.

1. **LICENSE TO SCALE**

**2.1 Grant of License.**  (a) Subject to the terms and conditions of this Agreement, Licensor grants to Licensee, and Licensee accepts, a revocable, limited, non-exclusive, non-transferable license to use the Scale without the right to sub-license the Scale.

 (b) All copies of the Scale and any derivative works shall be considered part of the Scale, and Licensee shall reproduce on all such copies Licensor’s proprietary rights notices in the forms set forth in the Scale delivered to Licensee or set forth in this Agreement, and shall not alter or remove any printed or on-screen copyright, trade secret, proprietary or other legal notices contained on or in copies of any Scale.

 (c) Licensee agrees that any copy or republication of the Scale shall include a notice of copyright in the following form:

 “© 2008 Research Foundation for Mental Hygiene, Inc.”

 (d) Allowable platforms include: tablet or web only

**2.2. Certification Process**.

* ERT will provide Licensee with a reference document on which Licensee can base its electronic implementation of the Scale (the “Implementation”). **Questions related to the Implementation can be emailed to certif-cssrs@clario.com.**
* Licensee will implement the Scale per the reference document.
* Licensee will submit screenshots of the Implementation to RFMH for review in US English. The screenshots should be emailed in a screen report document to Dr. Kelly Posner (kelly.posner@nyspi.columbia.edu), copying certif-cssrs@clario.com.
* Licensee must address any issues raised by RFMH relating to the Implementation’s content, layout, or formatting. ERT will not verify technological aspects of the Implementation, as this would require Licensee to submit proprietary intellectual property to ERT.
* If Licensee wishes to translate the Scale for a particular Implementation, Licensee will work directly with RFMH’s exclusive translations vendor, MAPI Research Institute (“MAPI”). Licensee will pay MAPI directly for those services.

Licensee may only administer an Implementation to trial participants once Licensee has received a written notification from ERT documenting and RFMH’s certification of the Implementation (such notice, a “Certification”). Licensee may not alter a certified Implementation without ERT’s prior written approval.

**2.3 Project Notification Form**

For each clinical research study or clinical research project, a separate Project Notification Form (“PNF”) will be prepared. A sample of the PNF format is attached as Exhibit A.

1. **FEES**

**3.1 Certification Fees and License Fees.**  Licensee shall pay Licensor a fee for each certified Implementation (the “Certification Fee(s)”), as described in Exhibit B. In addition, Licensee shall pay Licensor the license fee specified in Exhibit B for each administration of the Scale by Licensee to a trial participant (the “License Fee(s)”). Further details related to payment of the Certification Fees and License Fees are set forth in Section 4.1.

**3.2 Fixed Fees (As set forth in Exhibit B)**

1. One-Time Start-up Fee
2. Annual Support Fee

Details related to payment of the Start-up Fee and the Annual Support Fee are set forth in Section 4.1.

1. **PAYMENT**

**4.1 Payment.**  All payments due under this Agreement shall be made in U.S. dollars and paid in advance.

* The Start-up Fee is due on the Effective Date. This one-time, non-refundable fee covers the creation of an ongoing license for use of the Scale. Upon payment of the Start-up Fee, ERT shall provide Licensee with the source file(s) and existing translations for the Scale, in PDF and Word format, and Licensee may then implement the Scale. Upon payment of the Start-up Fee, ERT shall give Licensee the reference specification for the Scale, from which the Licensee may develop its Implementation-specific specification.
* The non-refundable Annual Support Fee is due on 1 January each year following the Effective Date. For the first year, the Annual Support Fee will be pro-rated depending on the Effective Date. This fee covers the continued right to use certified screenshots of the Scale in studies as often as needed during the year, while paying only License Fees for each study. The Annual Support Fee is due each year, even if the Licensee does not reach out to ERT to cancel the license or have any studies using the Scale during the applicable year.
* The Certification Fee is payable with submittal of Certification Application
* The License Fees are based on an estimated number of Scale administrations for the study in question and are pre-paid for each study. This fee is due for each time the Scale is administered to enrolled or screened patients in a study. If more administrations than predicted take place in the study, a reconciliation will be performed at the completion of the project.
* If an initiated project is cancelled within 90 days for whatever reason, the balance of unused, prepaid License Fees will be refunded less a $1,000 administrative fee. If the notification of cancellation is received after 90 days and Licensee received an invoice, the study specific license fee shall not be refunded.
* If an initiated project is cancelled within 90 days for whatever reason and the total amount of prepaid License Fees is less than $1,000, the prepaid License Fees will be refunded or waived. If the notification of cancellation is received after 90 days and Licensee received an invoice, the study specific license fee shall not be refunded.

**4.2 Taxes.**   Each party is responsible for its applicable duties and taxes, however designated, levied or based on this Agreement, including, without limitation, any personal property, retail, sales, goods and services, use or value added taxes and whether such taxes are now in force or subsequently levied.

1. **CONFIDENTIALITY**

**5.1 Publicity.**Licensee shall keep the material terms of this Agreement confidential. Licensee shall not use the name of RFMH, New York State Psychiatric Institute, New York State Office of Mental Health, Dr. Kelly Posner or any author of the Scale without RFMH’s prior written approval. Notwithstanding any other term or condition in this Agreement to the contrary, ERT may use Licensee’s name and logo in relation to the Scale for marketing purposes without Licensee’s prior approval; provided, however, that ERT will remove the name and logo upon written request of the Licensee. ERT will not publish, post, or distribute any other marketing material using such name and logo unless approved in advance by Licensee.

**5.2 Confidentiality.**  (a)  Confidential Information of each party will be used by the other party solely for the purposes permitted by this Agreement. All Confidential Information will be received and held in confidence by the receiving party, subject to the provisions of this Agreement for a period of ten (10) years from the date of receipt of such Confidential Information. Each party acknowledges that it will not obtain any rights of any sort in or to the Confidential Information of the other party as a result of such disclosure and that any such rights must be the subject of a separate written agreement(s).

 (b)  Each party will restrict disclosure of the other party's Confidential Information to those of its employees or agents to whom it is necessary to disclose such Confidential Information in connection with the purposes permitted under this Agreement provided, such employee or agents are bound by confidentiality restrictions similar to those set forth in this Agreement. Each party shall use reasonable efforts, including at least efforts fully commensurate with those employed by the party for the protection of its own Confidential Information, to protect the Confidential Information of the other party.

 (c)  Either disclosing party may at any time notify the receiving party that such receiving party must return to the disclosing party the disclosing party's Confidential Information. Each party hereby agrees to, within thirty (30) days of such notification: (i) return all documents and tangible items it or its employees or agents have received or created pursuant to this Agreement pertaining, referring or relating to the other party's Confidential Information; and (ii) return or certify (in a writing attested to by a duly authorized officer of such party) destruction of all copies, summaries, modifications or adaptations that such party or its employees or agents have made from the materials provided by the disclosing party.

(d)  Nothing herein shall prevent a receiving party from disclosing all or part of the Confidential Information as necessary pursuant to the lawful requirement of a governmental agency, during a judicial process or when disclosure is required by operation of law; provided that prior to any such disclosure, the receiving party shall use reasonable efforts to: (i) promptly notify the disclosing party in writing of such requirement to disclose; and (ii) cooperate fully with the disclosing party in protecting against any such disclosure or obtaining a protective order.

1. **PROPRIETARY RIGHTS**

**6.1 Title.** This Agreement does not convey to Licensee any ownership rights in the Scale (or any copies or derivative works thereof) but constitutes only a license to use the Scale in accordance with all of the terms of this Agreement. Title to the Scale (and each copy or derivative work thereof), and the right to grant licenses to use the Scale, shall at all times remain vested in Licensor.

1. **REPRESENTATIONS AND WARRANTIES.**

**7.1 Authorization; Enforceability.**  Each of Licensee and Licensor represent and warrant to the other that: (a)  it is a corporation duly organized, validly existing and in good standing under the laws of its incorporating jurisdiction and has all requisite corporate power and authority to enter into this Agreement; (b)  it is duly authorized by all requisite action to execute, deliver and perform this Agreement and to consummate the transactions contemplated hereby, and that the same do not conflict or cause a default with respect to such party's obligations under any other agreement; (c)  it has duly executed and delivered this Agreement; and (d) it is authorized to disclose any and all Confidential Information made available to the other party pursuant to this Agreement.

**7.2 Disclaimer.** EXCEPT AS EXPRESSLY PROVIDED HEREIN, ALL WARRANTIES WHETHER EXPRESSED OR IMPLIED, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE OR USE, ARISING OUT OF THIS AGREEMENT, ARE SPECIFICALLY DISCLAIMED, EXCLUDED, WAIVED AND NEGATED.

1. **RISK ALLOCATION**

**8.1 Limitation of Liability.** EXCEPT FOR INFRINGEMENT OF THE OTHER PARTY’S INTELLECTUAL PROPERTY RIGHTS OR BREACH OF CONFIDENTIALITY OBLIGATIONS UNDER SECTION 6, ANDEXCEPT AS OTHERWISE PROVIDED IN SECTION 8.2 WITH RESPECT TO THIRD PARTY CLAIMS, THE AGGREGATE LIABILITY OF EITHER PARTY FOR DIRECT DAMAGES ARISING OUT OF THIS AGREEMENT AND THE TRANSACTIONS CONTEMPLATED HEREBY SHALL BE LIMITED TO THE AGGREGATE AMOUNT PAID PURSUANT TO THIS AGREEMENT AS OF THE DATE SUCH CLAIM IS FINALLY RESOLVED. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER FOR LOST PROFITS, BUSINESS, REVENUES OR SAVINGS OR FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES IN CONNECTION WITH THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT, HOWEVER CAUSED, UNDER ANY THEORY OF LIABILITY.

**8.2 Indemnification.** Subject to the provisions of Section 8.3, each of Licensee and Licensor (each, an “Indemnifying Party”) will defend, indemnify and hold harmless the other party, its subsidiaries, parent corporations, affiliates, officers, directors, partners, shareholders, employees, agents, and their successors and assigns (collectively, the “Indemnitees”) from and against any claim, suit, demand, loss, damage, expense (including reasonable attorney’s fees of indemnitee(s) and those that may be asserted by a third party) or liability (collectively, “Losses”) imposed upon the Indemnitee(s) by any third party arising from or related to: (a) any negligence, gross negligence, fraud or willful misconduct by such Indemnifying Party (or its employees, agents or representatives) in performing its obligations under this Agreement; or (b) any material breach of the Indemnifying Party’s representations and warranties under this Agreement. The foregoing indemnification action shall not apply in the event and to the extent that a court of competent jurisdiction determines that such Losses arose as a result of any Indemnitee’s negligence, intentional misconduct or breach of this Agreement. Furthermore, for the avoidance of doubt and notwithstanding any other term or condition in this Agreement to the contrary, Licensor shall not be liable to Licensee for any Losses due to Licensee’s use of the Scale.

**8.3 Procedure.**  To receive the benefit of indemnification under Section 8.2, the Indemnitee must promptly notify the Indemnifying Party in writing of a claim or suit and provide reasonable cooperation (at the Indemnifying Party’s expense) and tender to the Indemnifying Party (and its insurer) full authority to defend or settle the claim or suit. Neither party has any obligation to indemnify the other party in connection with any settlement made without the Indemnifying Party’s written consent. The Indemnitee has the right to participate at its own expense in the claim or suit and in selecting counsel therefor. The Indemnitee shall cooperate with Indemnifying Party (and its insurer), as reasonably requested, at Indemnifying Party’s cost and expense.

1. **TERM AND TERMINATION**

**9.1 Term.** This Agreement shall take effect as of the Effective Date and shall remain in effect unless terminated in accordance with Section 9.2.

**9.2 Termination.** (a) Either party may terminate this Agreement or any PNF(s) at any time upon thirty (30) days’ notice to the other party in the event that the other party shall have breached any of its material obligations under this Agreement or such PNF(s) and shall not have cured such breach prior to the expiration of the thirty (30)-day period. Termination of any PNF(s) shall not result in termination of this Agreement or any other PNF(s), which shall remain in force until terminated as provided above. If termination of multiple PNFs is elected pursuant to Section 9.2, the opportunity to cure shall be available for each PNF and termination shall only apply to those PNFs with respect to which the breach is not cured.

 (b) Licensee may terminate any PNF(s) at any time upon immediate prior notice.

 (c) The parties may terminate this Agreement or any PNF at any time upon mutual written agreement of the parties.

**9.3 Effect of Termination.** (a) Upon termination of this Agreement or termination of any PNF(s) for any reason: (i) the parties will terminate all tasks for the affected PNF(s) in an orderly manner, as soon as practical and in accordance with a schedule mutually agreed to by the parties; and (ii) Licensee shall pay Licensor any monies due and owing up to the time of termination for Fees (as specified in the PNF(s)).

 (b) Upon termination (including expiration) of this Agreement each party shall return to the other party or certify in writing to the other party that it has destroyed all documents and other tangible items it or its employees or agents have received or created pertaining, referring or relating to the Confidential Information of the other party.

**9.4 Survival.** Sections 1 and 5 through 10 shall survive any termination or expiration of this Agreement.

1. **GENERAL PROVISIONS.**

**10.1 Issue Resolution.**  In the event that any dispute arises relating to this Agreement, the Representatives shall promptly meet and attempt to resolve same through good faith discussions. If the Representatives are unable to resolve any dispute to their mutual satisfaction within thirty (30) days after they commence discussions regarding same, and do not agree to extend the time for resolution of the issue at the end of their meeting, then they may by mutual agreement: (a) escalate the matter to higher levels in their organizations; and (b) if necessary, resort to arbitration in accordance with the rules of the American Arbitration Association, before one arbitrator appointed pursuant to such rules, prior to resorting to litigation if the parties do not mutually agree that such arbitration will be binding.

**10.2** **Governing Law.** This Agreement shall be governed and construed in accordance with the laws of the Commonwealth of Pennsylvania excluding any choice or conflict of law rules or provision that would result in the application of the substantive law of any other jurisdiction. Pennsylvania law will govern all questions related to the validity, interpretation or performance of this Agreement and all questions concerning any rights or obligations of the parties hereof.

**10.3 Amendment and Waiver.**  No provision of or right under this Agreement shall be deemed to have been waived by any act or acquiescence on the part of either party, its agents or employees, but only by an instrument in writing signed by a duly authorized representative of each party. No waiver by either party of any breach of this Agreement by the other party shall be effective as to any other breach, whether of the same or any other term or condition and whether occurring before or after the date of such waiver. This Agreement may not be amended or modified in any manner except by an instrument in writing that specifically identifies this Agreement and the provision intended to be amended or modified and is signed by a duly authorized representative of each party.

**10.4 Independent Contractors.**  Each party represents that it is acting on its own behalf as an independent contractor and is not acting as an agent for or on behalf of any third party. This Agreement and the relations hereby established by and between Licensee and Licensor do not constitute a partnership, joint venture, franchise, agency or contract of employment. Neither party is granted, nor shall neither party exercise, the right or authority to assume or create any obligation or responsibility on behalf of or in the name of the other party or its Affiliates.

**10.5 Assignment.**Neither this Agreement or any rights and obligations under this Agreement shall be assignable directly or indirectly by either party without the prior written consent of the other party; *provided*, that ERT may assign this Agreement to: (i) any Person to which such party transfers substantially all its assets or with which such party is consolidated or merged; (ii) any Person that owns a majority of the voting stock of such party; or (iii) a single Person of which such party owns a majority of the voting stock.

**10.6 Successors and Assigns.**This Agreement shall bind and inure to the benefit of the parties hereto and their respective successors and permitted assigns.

**10.7 Notices.**  Any notice or other communication required or permitted under this Agreement shall be in writing and shall be delivered by hand, first class mail, a nationally recognized overnight courier service, or sent by email transmission, to the Party at the address listed below, or to any other address subsequently specified by such Party in writing:

**LICENSOR:** **LICENSEE:**

eResearchTechnology, Inc. Licensee Name

 1818 Market Street, Suite 2600 Licensee Address1

 Philadelphia, PA 19103 USA Licensee Address2

 **Attn:** License Procurement Department **Attn:**

 **Email (preferred):** certif-cssrs@clario.com **Email:**

 **Invoicing email:**

Any such notice shall be effective: (i) in the case of hand delivery, when received; (ii) in the case of an overnight delivery service, on the next business day after being placed in the possession of such delivery service, with delivery charges prepaid; (iii) in the case of the mail, three days after deposit in the postal system, first class postage prepaid; and (iv) in the case of email transmission, when electronic indication of receipt is received or acknowledgement of a requested receipt is returned.

**10.8 Severability.**In the event any provision of this Agreement shall for any reason be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other term or provision hereof. The parties agree that they will negotiate in good faith or will permit a court or arbitrator to replace any provision hereof so held invalid, illegal or unenforceable with a valid provision which is as similar as possible in substance to the invalid, illegal or unenforceable provision.

**10.9 Entire Agreement.** The terms and provisions contained in this Agreement is the exclusive record of the parties’ agreement and understanding. Licensee and Licensor intend the terms and conditions of this Agreement to constitute the final, complete, exclusive and completely integrated terms and conditions to which they intend to be bound and the parties do not intend to be bound by any other agreements, promises, conditions or representations, written or oral, of whatsoever kind or nature.

**10.10 Counterparts.**This Agreement may be executed in multiple counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. In making proof of this Agreement, it shall not be necessary to produce or account for more than one such counterpart.

**10.11 Force Majeure.** Except as otherwise provided in this Agreement, in the event that a delay or failure of a party to comply with any obligation, other than a payment obligation, created by this Agreement is caused by a Force Majeure condition, that obligation shall be suspended during the continuance of the Force Majeure condition.

**Both parties represent that they have read this Agreement, understand it, and agree to be bound by the terms and conditions stated herein.**

IN WITNESS WHEREOF, and intending to be legally bound, the parties have caused this Agreement to be executed on their behalf by their duly authorized representatives intending it to take effect as of the Effective Date. Upon execution, email the executed License Agreement to certif-cssrs@clario.com.

ERESEARCHTECHNOLOGY, INC.,

A CLARIO COMPANY LICENSEE

By\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ By\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Authorized Signature Authorized Signature

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name (Print) Name (Print)

Title \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Title \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**EXHIBIT A**

**The PNF attached shows an example only. The original Excel sheet contains formulas to calculate license fees based on the total administrations entered and does not need to be signed off.**

**EXHIBIT B**

**FEES**

**License Fees.**  Licensee shall pay to Licensor License Fees in the amount of ***$3.00 per administration*** (electronic ClinRo) for use of the Scale.

**Administration Fees:**

1. One-Time Start-up Fee: $40,000
2. Annual Support Fee: $7,500
3. Certification Fee: $5,000 per English certification