Qr code

Description automatically generated**SHEEHAN IRRITABILITY SCALE**

**COPYRIGHT LICENSE AGREEMENT**

Directions: **USE TAB KEY** on your keyboard to navigate this document

All items in yellow are REQUIRED, it will delay your request if you leave things blank.

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| **Licensee** **Name & Institution** | INSERT LICENSEE NAME |
| **Study Sponsor** | INSERT SPONSOR NAME |
| **Address** | INSERT ADDRESS INCLUDE COUNTRY |
| **Email(s)** | INSERT EMAIL |
| **Licensee** **Phone Number** | INSERT LICENSEE PHONE # |
| **Primary Investigator (PI)** | INSERT PI NAME |
| **SIS Timeframe(s)** (e.g., timeframe for screen, weekly visit, follow-up visit) | 1**.**  2. 3. |
| **Study ID/NCT #** | INSERT NCT #, Protocol #, IRB #, NA if non-research. |
| **Total Requested** | 0 THIS WILL AUTOCALCUATE FROM APPENDIX 1 |

This license agreement (hereinafter the “**Agreement**”) is effective upon execution by both Parties (the “**Effective Date**”), by and between **Dr. David V. Sheehan** (hereinafter the “**Copyright Holder**” **or “Dr. Sheehan”**), 611 Warren Rd, Lutz, FL 33548, USA, and the above-named Licensee Name and Licensee Institution (hereinafter the “**Licensee**”) (each individually, a “**Party**”, and collectively, the “**Parties**”).

WHEREAS Copyright Holder owns the registered copyrights to the Sheehan Irritability Scale (hereinafter the **“SIS**”):

WHEREAS Licensee desires to license the SIS:

NOW THEREFORE, in consideration of the premises and the mutual promises and covenants contained in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

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| Section 1. License |

Subject to the terms and conditions outlined in Sections One (1) through Fifteen (15) that govern this License and Appendix 1 of this Agreement, the Copyright Holder grants to the Licensee, and only to those directly involved in the research study identified in Appendix 1 of this Agreement, a non-exclusive, world-wide license to:

1. Use and reproduce in paper format and its requested non-English Language translations approved by Copyright Holder per translation agreements with MAPI / ICON Language Services, but not in any other electronic, mobile, digital, or computer formats (“Excluded Digital Formats”), the SIS for the study listed in Appendix 1 of this Agreement only and in accordance with the number of copies approved for use in Appendix 1 of this Agreement by the Copyright Holder, and as designated by the terms and conditions in this Agreement.
2. Only use the translation of the SIS directly provided by the Copyright Holder or MAPI / ICON Language Services (hereinafter “**MAPI**”) (see Section 3 below) in paper format for the trial listed in Appendix 1 of this Agreement, but not in any Excluded Digital Formats, and not use these translations in any other study other than that listed in Appendix 1 of this License Agreement, without a separate License Agreement signed by the Copyright Holder. Translations from other studies are not permitted to be used in the study listed in Appendix 1 without prior written permission from the Copyright Holder.
3. Use all data and results generated from the use of the SIS.

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| Section 2. Limitations |

The rights (License) granted under Section 1 above are limited to the number of licensed administrations of the SIS for purposes of Licensee’s clinical trials or clinical use defined in Appendix 1 of this Agreement hereinafter. In addition to the above-mentioned limitations, Licensee or where applicable the clinical research organization (CRO), or contract research organization (CRO), or scale management organization, or the sponsor involved in this study must be listed in Appendix 1 of this Agreement and will:

1. Include the following acknowledgment in all reproductions of the SIS:

© Copyright 1999-2023 David V Sheehan. The SIS may not be used by anyone without prior written permission. Dr. Sheehan may be contacted at [davidVsheehan@gmail.com](mailto:davidVsheehan@gmail.com) for permission to use the SIS in paper format.

1. Refrain from reproducing any part of the SIS or its translations in any publication or in any Excluded Digital Formats copied, derived, or otherwise resulting from the use of the SIS in paper format. This license does not provide such consent.
2. Refrain from posting the SIS provided under this license on any website and refrain from sharing the SIS with anyone beyond those directly involved in the study as listed in Appendix 1 of this Agreement.
3. Not use within this study any other formats or versions of Dr. Sheehan’s intellectual property except under a license directly from Dr. Sheehan. The Parties acknowledge and agree that this clause is intended to promote patient safety, interrater reliability, data integrity, and public health by avoiding the use of multiple formats or versions of Dr. Sheehan’s intellectual property within the same study.
4. Refrain from reproducing the SIS or any parts of it in any training materials or using it for any rater training in the study listed in Appendix 1 below. This is not a license for use of the SIS in rater training. To arrange for rater training directly from Dr. Sheehan, the developer and copyright holder, please contact: [training@harmresearch.org/](mailto:training@harmresearch.org/) The use of paper copies of the SIS under this Agreement, for inclusion in any training materials, or in rater training, or in any documents (including but not limited to slides, presentations, print outs) and each view of these documents requires payment for each copy so provided, to each user/recipient. Such trainee users will be bound by the same terms and conditions as reflected in this License Agreement.
5. If training is required for the study listed in Appendix 1 of this License Agreement, the Licensee, Sponsor and the Primary Investigator listed in this License Agreement understand that Copyright Holder has not authorized any Third Party to train on the use of SIS for the study identified in Appendix 1. Licensee can arrange training by Dr. David V. Sheehan and purchase this training through Dr. Sheehan’s scales website by contacting [training@harmresearch.org](mailto:training@harmresearch.org). Licensee agrees that they will refrain from reproducing or editing any training materials or using Certificates of Completion from Dr. Sheehan for raters from other studies as documentation of training for the study listed in Appendix 1. If training is needed, Licensee must pay for all copies of the paper format used in training. The Licensee, Sponsor and the Primary Investigator listed in this License Agreement agrees to ensure that Raters receive training, or any information (e.g., training materials) of training that is pertinent to the staff's role in the study.
6. Complete an audit for any overages or unauthorized use, upon request from Dr. Sheehan.
7. Transmit to the Copyright Holder a copy of all final translations of the SIS.

Licensee acknowledges and agrees that any violation of subsections 1 (a), 1(b), 2(a), 2(b), 2(c), 2(d), 2(e), or 2(h) of this Agreement will constitute a material breach of this Agreement and may result in irreparable harm to Dr. Sheehan’s interests, triggering Dr. Sheehan’s rights and remedies under Sections 9 and 10 of this Agreement.

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| Section 3. Instrument Access |

Promptly after the Effective Date, the Copyright Holder shall provide to Licensee access to the SIS in the English source language in paper form for any uses, or in fixed-pdf form or paper form for use in clinical or academic research trials or studies.

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| Section 4. Non-English Translations |

The non-profit Mapi Research Trust (MAPI) / ICON Language Services, 27 rue de la Villette, 69003 Lyon, France, is the sole translation service for existing ***non-English translations*** for all rating scales and diagnostic interviews that Dr. Sheehan distributes directly. Dr. Sheehan has collaborated closely with MAPI on these translations for over 15 years and continues to do so. This is to ensure the production of consistent and conceptually equivalent translations of the SIS and its variants and of the Copyright Holder’s scales, and to be able to provide linguistic validation and certification of these translations. MAPI / Icon Language Services will not distribute the ***English source language*** *version* of the SIS, which is available from Dr. Sheehan under this Agreement.

Licensee is required under this Agreement to get a license from Dr. Sheehan for all the administrations to be done in ALL languages in the study/clinical setting identified in Appendix 1 below and to pay the invoice to Dr. Sheehan for this license.

If Licensee needs a translation beyond the English source version, Licensee should wait to reach out to MAPI / Icon Language Services until after this License Agreement is fully executed and the invoice paid. (MAPI will not provide translations under this License Agreement, without evidence of a fully executed license from Dr. Sheehan for ALL administrations in ALL languages.

Requests to access existing ***non-English translations*** must be submitted through Mapi Research Trust’s ePROVIDE platform at  <https://eprovide.mapi-trust.org/> using the following process:

1. Go to [Submit a request](https://eprovide.mapi-trust.org/my-eprovide/my-requests/new)

2. If you haven't registered yet, you'll be asked to [sign up for free](https://eprovide.mapi-trust.org/register)

3. Complete the request form. Please attach a copy of the signed and fully executed license agreement.

MAPI / Icon Language Services may charge its own usual fees for this work, which may include separate fees paid to Dr. Sheehan or other subject matter experts to the extent such services are necessary to prepare reliable and valid translations and to provide the associated linguistic validation certificates associated with these translations for regulatory, IRB, or any other audit needs of the user.

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| Section 5. License Fee |

Licensing the SIS shall be in accordance with the following 4 tier pricing model:

1. $4.00 per administration for the **initial** **purchase** (in other words requesting permission prior to administrations taking place)
2. $12.00 per administration for any **deferred** **purchase(s)** (in other words declining to pay for licenses per the ratios recommended in Appendix 1 of this Agreement and subsequently needing additional licenses beyond the number initially requested in the “initial purchase” prior to any administrations taking place).
3. $20.00 per administration for any **delinquent** **purchase(s)** (in other words (1) failure to pay within the payment terms in Section 6; (2) Failure to obtain a fully executed license agreement from the Copyright Holder prior to any administrations or use of the SIS in your research study or clinical practice) – (for example, in line with numbers used and found reported in www.clinicaltrials.gov reporting and / or publications reporting the study results or discovery of use in a clinical setting without payment in advance of use).
4. $24.00 per administration for any **overdue payment of delinquent** **purchase(s)** (in other words failure to pay a delinquent invoice within 30 days of receipt of delinquent invoice.)

The Copyright Holder licenses the SIS to Licensee, for a total overall fee of USD $ INSERT TOTAL (United States Dollars) for the number of licenses granted in Appendix 1 of this Agreement and in accordance with the 4-tier license model above. The Copyright Holder will invoice Licensee for this amount promptly following the Effective Date.

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| Section 6. Payments Terms; Product Use |

Licensee agrees to pay for all amounts under this Agreement within thirty (30) days of the applicable invoice date from the Copyright Holder. If Licensee’s account is past due, Copyright holder may terminate this Agreement and require any further licensing on a cash-in-advance basis. The invoice number provided by the Copyright Holder to the Licensee shall be included with this payment for tracking purposes. Licensee further agrees that all use of the Copyright Holder’s licenses will be for the purposes contemplated in this Agreement and per Appendix 1 and the SIS or any of its translations shall not be re-sold or otherwise diverted.

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| Section 7. Intellectual Property |

The Parties agree that, as between David V. Sheehan MD, (Copyright Holder and Trademark Holder) and Licensee, the:

1. Copyright Holder shall own all right (including Copyright and Trademark) title, and interest in and to the SIS that is the subject of this License as listed in Appendix 1, including any translations used under this Agreement, and
2. Licensee shall own all right (including Copyright and Trademark) title, and interest in and to all results, analyses, correlations, trends, and hypotheses that are generated by or on behalf of Licensee using the SIS under the terms and conditions of this Agreement (hereinafter the “**Results**”).

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| Section 8. Representation and Warranties |

The Copyright Holder represents and warrants that he currently owns and is the Copyright holder and has the right to grant Licensee the license set forth in this Agreement. The SIS is a clinical decision support instrument. It is not a diagnostic test.

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| Section 9. Term and Termination |

This Agreement is effective on the Effective Date and shall continue for a period (1) Year from the Effective Date (“Initial Term”). Following this Initial Term, this Agreement shall automatically renew for subsequent one (1) year periods (each, a “Renewal Term”), unless the License is earlier terminated pursuant to Section 9 (the “**Term**”).

1. Licensee may terminate this Agreement at any time upon written notice to the Copyright Holder and including the relevant invoice number provided by the Copyright Holder to the Licensee. Upon termination an audit by the Licensee of all uses of the SIS must be carried out by Licensee and any usage of the SIS that has not already been paid for must be paid for per the terms in Section 5c within the payment terms under Section 6 of this Agreement.
2. Copyright Holder may terminate this Agreement if Licensee is in breach of any obligation and such obligation remains uncured to the reasonable satisfaction of Copyright Holder within twenty (20) days of the date upon which Copyright Holder provides notice of breach to Licensee.
3. Copyright Holder may also terminate this Agreement if payment is overdue.
4. Copyright Holder may also terminate this Agreement if the Licensee administers the SIS more times than is covered by this Agreement without prior written permission.
5. Copyright Holder may terminate this Agreement if the Section 11: Confidentiality Information section [below] is breached by the Licensee.

Upon expiration or earlier termination of this Agreement, the receiving Party will, at the written request of the other Party, return or destroy (at the disclosing Party’s sole discretion) all Confidential Information of the disclosing Party then in its possession or control and all copies and embodiments of such Confidential Information, provided that the receiving Party may retain one copy in its confidential legal files for archive purposes and may use such copy only for legal purposes (including exercising the receiving Party’s rights under this Agreement).

Section 2, Section 5, Section 6, Section 7, Section 8, Section 10, Section 11, Section 12, Section 13, Section 14.9, Section 14.11, and Section 14.12 shall survive expiration or termination of this Agreement.

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| Section 10. Limitation of Liability |

This Section 10, “**Liability**” means anyliability, whether under contract, tort, or otherwise, including for negligence.

1. Nothing in this Agreement excludes or limits either Party’s liability for: (1) fraud or fraudulent misrepresentation; or (2) matters for which liability cannot be excluded or limited under applicable law.
2. Subject to Section 10a, the Copyright Holder shall not be liable to the Licensee for any indirect, consequential, special, reliance, or punitive damages, whether liability is asserted in contract, tort (including negligence and strict product liability), indemnity or contribution, and irrespective of whether the Licensee or any representative of the Licensee has been advised of, or otherwise might have anticipated the possibility of, any such loss or damage.
3. The Copyright Holder is not liable for: (1) Licensee induced misuse or improper operation of the product; (2) product that has been modified without Copyright Holder written consent; (3) any damage or problem resulting from Licensee failure to adhere to Copyright Holder directions for use and training.
4. Subject to Section 10a and 10b, the Copyright Holder’s aggregate liability arising out of, or relating to this Agreement, will not exceed USD $1,000.00
5. The Parties acknowledge and agree that Licensee’s uncured breaches of this Agreement may result in irreparable harm to Dr. Sheehan’s interests; therefore, Dr. Sheehan may pursue immediate injunctive relief from a court with jurisdiction in the event of such breaches.

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| Section 11. Confidential Information |

Both Parties acknowledge and agree that they may have access to Confidential Information of the other Party. For purposes of this Agreement, “**Confidential Information**” shall mean (a) all confidential, proprietary, or trade secret information, property, or material and any derivatives, portions, or copies thereof, including without limitation, information resulting from the Results; (b) the business practices, plans, or relationships of either Party; (c) any other information that either Party designates as Confidential Information including the information provided by the Licensee in Appendix 1 of this Agreement, and (d) emails and all other written communications from Dr. Sheehan associated with this License Agreement. Neither Party except with the express prior written consent of the other, shall directly or indirectly communicate, disclose, or divulge to any third party any such Confidential information. Each Party shall keep all Confidential Information in strict confidence for a period of ten (10) years from completion of each Protocol. The obligations under this Section 11 with respect to Confidential Information shall survive for a period of five (5) years from the expiration or termination of this Agreement.

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| Section 12. Permitted Disclosures |

Notwithstanding the obligations set forth above, either Party may disclose Confidential Information to any of its employees who need to receive the Confidential Information to perform its obligations under this Agreement. The restrictions on Confidential Information shall not apply to any Confidential Information that (a) was known prior to receipt from the other Party as demonstrated in written records; (b) becomes a matter of public information or publicly available through no fault of either Party; (c) is acquired from a third party entitled to disclose the information; (d) is developed independently by either Party; and (e) is required to be disclosed pursuant to law, regulation, or court order.

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| Section 13. Publicity and Use of Name |

Except as required by applicable law and as otherwise expressly permitted under this Agreement, neither Party shall use the name of the other Party or of any staff member, employee, student, or agent of the other Party or any adaptation, acronym, or name by which the other Party is commonly known, in any advertising, promotional or sales literature or in any publicity without the prior written approval of the Party or individual whose name is to be used. Except as required by applicable law, neither Party shall disclose any of the Parties’ activities hereunder or the subject matter hereof without the prior written consent of the other Party.

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| Section 14. Miscellaneous |

**14.1. Notices.**  All notices of termination or breach must be in English, in writing and addressed to the other Party or the Party’s Legal Department, or, if Copyright Holder is an individual, directly to Copyright Holder. The address for notices to Licensee or the Licensee’s Legal Department is Insert Legal Department Address and Email

**14.2. Assignment.**  Neither Party may assign any part of this Agreement without prior written consent of the other, except to an affiliated company or a third party that succeeds to all or substantially all of the assigning Party’s business or assets relating to this Agreement, whether by sale, merger, operation of law or otherwise, provided that: (a) the assignee has agreed in writing to be bound by the terms of this Agreement; and (b) the assigning Party has notified the other Party of the assignment. Any attempt to assign any part of this Agreement other than as permitted under this Section is void.

**14.3. No Waiver.** Neither Party will be treated as having waived any rights by not exercising (or delaying the exercise of) any rights under this Agreement.

**14.4. No Agency.** This Agreement does not create any agency, partnership, joint venture, or employment relationship between the Parties.

**14.5. Counterparts.** The Parties may execute this Agreement in counterparts, including facsimile, PDF, and other electronic copies, which taken together will constitute one instrument.

**14.6. Amendments.**  Any amendment must be in writing, supplemented by the original Agreement and invoice number(s), signed by both Parties, and expressly state that it is amending this Agreement.

**14.7. Entire Agreement.**  This Agreement sets out all terms agreed between the Parties and supersedes all other agreements between the Parties relating to its subject matter including any prior agreement relating to Confidential Information insofar as it relates to Confidential Information disclosed under this Agreement. In entering into this Agreement neither Party has relied on or will have any right or remedy based on any statement, representation, or warranty (whether made negligently or innocently) except those expressly set out in this Agreement.

**14.8. Severability.**  If any term (or part of a term) of this Agreement is invalid, illegal, or unenforceable, the rest of the Agreement will be construed to give maximum effect to all the remaining provisions.

**14.9. Governing Law and Venue.**  All claims arising out of or related to this agreement will be governed by Florida law and will be litigated exclusively in the federal or state courts of Hillsborough County, Florida, USA. The Parties consider this Agreement to have been made there and acknowledge and agree that Dr. Sheehan’s collection of intellectual property that is the subject of this license is based there; therefore, Licensee consents to personal jurisdiction in those courts.

**14.10.** **Adherence to Anti-Corruption Laws and Other Applicable Laws.**  Neither party in the performance of this Agreement shall take any action that would be illegal under any applicable rule, regulation, or law including anti-corruption laws (collectively “Anti-Corruption Laws”) and shall avoid practices that are unlawful or unethical. Without limiting the foregoing, neither party shall make any payments, or offer or transfer anything of value, to any government official or government employee, to any political party official, or candidate for political office, or to any other third party related to the transaction, in a manner that would violate Anti-Corruption Laws.

**14.11. Survival**. The following provisions shall survive any termination of this Agreement: (a) any payment due and payable as of the date of termination; (b) any provision expressly stated to survive; and (c) each of the paragraphs set forth below.

**14.12. Return Policy.** The SIS provided under this Agreement is not returnable. However, if Licensee decides not to use the SIS and contacts Dr. Sheehan within 30 days from the invoice date, Dr. Sheehan will provide a credit on Licensee’s next purchase. All purchases are final.

**14.13** **Communication.** Licensee agrees to receive email communications from Copyright holder.

\* \* \* APPENDIX 1 TO FOLLOW \* \* \*

**APPENDIX 1**

Use specific to this Agreement is defined below.

Permission has been granted to Licensee, and only to those directly involved in the study listed in Appendix 1 of this Agreement for the study listed in this Agreement, to use the SIS 7.0.2 (8/8/16 version) in accordance with the number of copies approved for use in Appendix 1 of this Agreement by the Copyright Holder, and as designated by the terms and conditions in this Agreement, and signed by Dr. David V. Sheehan as Copyright Holder, for the following setting **ONLY**, until further request and permission has been granted for studies not listed hereinafter:

**Please fill out in its entirety to not delay your request. If something is left blank or unclear it will delay your request. For non-research please go to section B.**

Directions: **USE TAB KEY** on your keyboard to navigate this document

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| **Product / Compound of Study**  = INSERT PRODUCT STUDYING, NA if none | | **Study Id Number / IRB # / ClinicalTrials.gov NCT ID # / EudraCT # / Grant #**  *THIS WILL AUTOCALCUATE FROM PAGE 1*  **=**INSERT NCT #, Protocol #, IRB #, NA if non-research. |
| **Study Name on Protocol**  = INSERT TITLE | | **Principal Investigator/Primary Clinician:**  *THIS WILL AUTOCALCUATE FROM PAGE 1*  = INSERT PI NAME |
| **Study Sponsor:**  *THIS WILL AUTOCALCUATE FROM PAGE 1*  = INSERT SPONSOR NAME | | **Estimated start date of study:**  = MONTH/DAY/YEAR |
| **List all Third-Party Organizations for study. Insert NA if none exists.**  Clinical Research Organization/ Contract Research organization (CRO)= INSERT NAME  Rater Training Vendor=INSERT NAME  Scale Management Vendor= INSERT NAME  Institutional Review Board (IRB) or Ethics Review Board = INSERT NAME | | **Languages requested for study:**  **=** INSERT LANGUAGES REQUESTED |
| 1. Will the SIS be done at the screening visit and / or as part of recruitment and / or intake? **(Answer 1)** | | 1. Projected number of subjects / patients to be randomized to all treatments / study medications at the baseline visit per protocol / clinical care setting.   = 0 **(Answer 2)** |
| 1. **Research studies only** | How many patients do you plan to screen with the SIS at the screening visit to get the yield of the number randomized at the end of the baseline visit? What is the most accurate way to calculate this number? See below:  Take the number you intend to randomize *at the end* of the baseline visit. Multiply that number by 2 or by 3. If you intend to randomize 100 to the study treatment at the end of the baseline visit, you will need to screen approximately 200 with the SIS at the beginning of the screening visit to get this yield. This ratio is usually at least a 2:1 ratio in Major Depressive Disorder or Anxiety Disorder Studies or at least a 3:1 ratio in schizophrenia studies. *This is the best estimate of the number of* SIS *to be done at the screening visit.*  *This ratio is not the same as a “study drop out” ratio which reflects the % of patients who drop out after the baseline visit. The (2:1 or 3:1) ratio above is the ratio reflecting the % of patients screened with the* SIS *and who still meet eligibility criteria to be randomized to treatment at the end of the baseline visit. 1*   1. Given the above information how many patients do you plan to screen with the SIS at the screening visit to get the yield of the number randomized at the end of the baseline visit? *(Take “Answer 1” and multiply by 2 at minimum for recommended 2:1 ratio.* ***Based on your answer to “Answer 1” your recommended number is:*** 0)   = 0 (**Answer 3)**   1. I understand that if I do not take the recommended 2:1 ratio that I am liable for use over the approved licensed amount per the terms in this contract (please read Section 5 carefully) **(Answer 4)** 2. Do you plan to administer any additional SISs at the baseline visit and later in the study?   **(Answer 5)**   1. If YES, how many additional times per subject? = 0 **(Answer 6)** 2. Multiply Answer 2 by Answer 6 = 0 **(Answer 7)** 3. How many SISs will be administered *in total* in this study? This includes the total number of SIS you are requesting permission to use at the screening visit plus at all subsequent visits. **(Answer 3 + Answer 7)** = 0 **(Answer 8)** 4. Do you plan to print any additional copies of the SIS or use in any training? If so, please insert that number here **=** 0 **(Answer 9)**   TOTAL SIS requested for the study listed in Appendix 1 of this Agreement **(Answer 8 + Answer 9 = FINAL REQUEST) =** 0  (Please update Total Overall Fee in Section 5 above to align to this request) | |

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| 1. **Non-research,**   **Clinical settings only** | If this is for use in a clinical setting, rather than for use in a research study, how many SISs do you plan to administer? If you fill this section in you do not have permission to use the SIS in any research, clinical trial, or publication.  = 0  (Please update Total Overall Fee in Section 5 above to align to this request) |

**Non-Profit settings:**

Note: *Non-profit institutions* sometimes assume that the license fee does not apply to them because they are “not-for-profit”. This licensing fee does apply to non-profit institutions.

**For-Profit settings:**

The use of the SIS instruments for any “for profit” use, for any gain, or in any “for profit” setting is not free and requires a fully executed license agreement in writing and payment of a per use licensing fee.

Dr. Sheehan, the Copyright Holder, may be contacted for a license for the use of the SIS in paper format at [davidVsheehan@gmail.com](mailto:davidVsheehan@gmail.com)

The key recommended **citations** for the SIS are:

1. Khan SA, Revicki DA, Hassan M, Locklear JC, Friedman LA, Mannix S, Tummala R, Eriksson H and Sheehan DV. Assessing the reliability and validity of the Sheehan Irritability Scale in patients with major depressive disorder. *J Clin Psychiatry* 2016 ;77(8) :1080-1086. 10.4088/JCP.14m09719.
2. Mannix S; Hassan M, Tummala R, Locklear JC, Revicki DA, Khan S, Dunbar GC, Eriksson H, Sheehan, DV. "Content validity of the Sheehan Irritability Scale in patients with major depressive disorder." *International clinical psychopharmacology* 31.2 (2016): 110-117.

A recommended **citation** to assist in understanding how to calculate the attrition rate from first contact through the entire course of a clinical trial:

1. Roy, S., Patel, S., Sheehan, K. H., Janavs, J., & Sheehan, D. (2008). Efficacy of print advertising for a bipolar disorder study. Psychopharmacology Bulletin, 41(1), 136-141.

\* \* \* SIGNATURE PAGE TO FOLLOW \* \* \*

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| Section 15. Contract Authorization |

***When this document is signed by both Dr. David Sheehan, Copyright Holder, and Licensee, this document will be a legal and binding contract.***

By signing below, (1) each party hereby agrees that this Agreement (together with Appendix 1 hereto) sets out all terms agreed between the Parties and supersedes all other agreements between the Parties relating to its subject matter, and (2) Licensee acknowledges receipt of the License Agreement. (3) Licensee further represents that the person signing this Agreement is duly authorized by Licensee to enter into this Agreement on behalf of Licensee. (4) Licensee agrees that they have made all Third Parties involved in the study listed in Appendix 1, including but not limited to Sponsor, CRO and Rater Training Vendor, aware of License Agreement Terms and aware that they are bound by these terms for the study listed in Appendix 1 of this License Agreement.

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| **“Copyright Holder”**  **David V. Sheehan MD, MBA, FACPsych, DLFAPA** | **“Licensee”**  INSERT COMPANY NAME |
| Signed By:  Name: David V Sheehan MD, MBA, FACPsych, DLFAPA  Title: Copyright holder  Phone: (813) 956-8437  Email: davidVsheehan@gmail.com  Date: | Signed By:  Name:  Title:  Phone:  Email:  Date: |
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**Please email your partially executed copy of this Agreement to the attention of Dr. David V. Sheehan, the Copyright Holder at:** [**davidVsheehan@gmail.com**](mailto:davidVsheehan@gmail.com)Dr. Sheehan will review it. If is acceptable he will then fully execute the license agreement and return it to the Licensee.