Completing a License Agreement
At No Cost For Those Eligible

If you need these steps translated, please go to
https://harmresearch.org/index.php/about-us/contact-us/license-agreement-tutorials/#How%20to%20Complete%20an%20At%20No%20Cost%20for%20Those%20Eligible%20Version%20License%20Agreement and select your preferred language from the top right corner of the webpage.
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for use in paper or pdf format of either the Standard or of the Psychotic Disorders
versions of the Mini International Neuropsychiatric Interview -
The M.I.N.I. 7.0.2 (8/8/16 version)

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”), 611 Warren Rd, Lutz, FL 33548, USA, and XXXX, a XXXX e.g. Delaware limited liability company having an office at XXXX [ADDRESS], (hereinafter the “Licensee”) (each individually, a “Party”, and collectively, the “Parties”).

* * *

WHEREAS Copyright Holder controls the standard and psychotic disorders versions of ‘Mini International Neuropsychiatric Interview - the M.I.N.I. 7.0.2 (8/8/16 version) (hereinafter collectively the “M.I.N.I.”);

WHEREAS Licensee desires to license the M.I.N.I.;

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:

* * *

1. License. Subject to the terms and conditions of this Agreement, the Copyright Holder grants to the Licensee, as well as to Licensee’s affiliated companies, subcontractors, and research partners (including, but not limited to, XXXX), an exclusive, world-wide license to:

   a. Use and reproduce in paper format and in PDF format, but not in other electronic or computer format, the M.I.N.I. and its existing translations;

   b. Use the translations of the M.I.N.I. in the languages approved by the Copyright Holder, in collaboration with MAPI Language Services (hereinafter “MAPI” ) (see Section 3 below) for each trial as requested;

   c. Use all data and results generated from the use of the M.I.N.I.; and

   d. Use the M.I.N.I. in rater training.

2. Limitations. The rights (license) granted under Section 1 above are limited to the number of licensed administrations of the M.I.N.I. for purposes of Licensee’s clinical trials defined in Appendix 1 hereinafter.

In addition to the above-mentioned limitations, Licensee will:

   a. Include the following acknowledgment in all reproductions of the M.I.N.I.:
"© Copyright 1992-2016 Sheehan DV. All rights reserved. May be reproduced only with the permission of Dr. David V. Sheehan, copyright holder. For permission contact davidsheehan@gmail.com“.

b. Transmit to the Copyright Holder (in MS Word and/or PDF format) a copy of any and all final translations of the M.I.N.I.; and

c. Refrain from reproducing any part of the M.I.N.I. or its translations in any publication resulting from the use of the M.I.N.I., without the prior written consent of the Copyright Holder.

d. Refrain from posting the M.I.N.I. on any website.

3. Non-English Translations. MAPI Language Services, is the exclusive coordinating center to ensure the production of consistent and conceptually equivalent translations of the M.I.N.I. and its variants and of the Copyright Holder’s scales, and to provide linguistic validation and certification of these translations and should be contacted directly for this purpose. MAPI may charge its own usual fees for this work.

The non-profit Mapi Research Trust, 27 rue de la Villette, 69003 Lyon, France, is the sole organization authorized to distribute existing non-English translations or to request new translations of the M.I.N.I. and its variants. All 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
2. If you haven’t registered yet, you’ll be asked to sign up for free
3. Complete the request form. You should attach a copy of the signed and fully executed license agreement or attach any other relevant documents, if need be.

4. Instrument Access. Promptly after the Effective Date, the Copyright Holder shall provide the M.I.N.I. to Licensee in PDF or paper format.

5. License Fee. The following 3 exceptions are granted a “no charge” license fee, but all must first sign this license agreement, and have it approved and counter-signed by Dr. Sheehan:

1. If the study is designed specifically and exclusively to assist refugees or victims of terrorism.

2. If the MINI is used exclusively and only as part of an undergraduate or graduate school research thesis or research dissertation, and not as part of anyone else’s research or data gathering, and the total number of administrations cannot exceed a total of 150 administrations. For this exception to the licensing fee, the student must be the person completing and signing the license agreement. The license is granted to the student for this purpose and not to their institution / mentor / supervisor.

3. If you are a professor using the instrument in the context of directly training students in your class, you are eligible for the "no charge” license to use it in the context of directly training students in your class - as long as it is properly cited and proper copyright attribution is given on any documents.

In completing and signing this form the Licensee certifies that their licensing and use of the M.I.N.I. qualifies for the “no charge” use under one of the above 3 exceptions in Section 5 above.
If the Licensee is not one of the above exceptions, the Licensee should instead complete the Standard License Agreement rather than this one.

Note: *Non-profit institutions* sometimes assume that the license fee does not apply because they are “not-for-profit”. This licensing fee applies to all uses that do not meet one of the above 3 criteria.

6. **Restriction on the “no charge use for those eligible”**. The Licensee agrees that this approval covers the Licensee’s personal research study, or use as identified in this license agreement, and does not cover use of M.I.N.I. for any other research or clinical purpose or training purpose beyond this.

7. **Intellectual Property**. The Parties agree that, as between the Copyright Holder and Licensee, the:
   a. Copyright Holder shall own all right, title, and interest in and to the M.I.N.I. including any translations, and
   b. Licensee shall own all right, title, and interest in and to all results, analyses, correlations, trends, and hypotheses that are generated by or on behalf of Licensee using the M.I.N.I. under the terms and conditions of this Agreement (hereinafter the “Results”).

8. **Representation and Warranties**. The Copyright Holder represents and warrants that he currently owns and will maintain the right to grant Licensee the licenses set forth in this Agreement.

9. **Term and Termination**. This Agreement is effective on the Effective Date and shall continue perpetually, unless earlier terminated in accordance with this Section (the “Term”).
   a. 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.
   b. If the Licensee materially breaches (the “Breaching Party”) any of its obligations hereunder, the Copyright Holder (the “Non-Breaching Party”) may terminate this Agreement at any time upon written notice to 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 7, Section 10, Section 12, Section 13, and Section 14.9 shall survive expiration or termination of this Agreement.

10. **Limitation of Liability**. In this Section 10, “Liability” means any liability, whether under contract, tort, or otherwise, including for negligence.
   a. 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.

b. 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.

c. 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

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; and (c) any other information that either Party designates as 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.

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 in order 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.

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 other 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.


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 [ADDRESS AND EMAIL].
14.2. **Assignment.** Neither Party may assign any part of this Agreement without the 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. In entering into this Agreement neither Party has relied on, nor neither Party 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 remain in effect.

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 consent to personal jurisdiction in those Courts.

14.10 **Adherence to Anti-Corruption Laws.** Neither party shall perform any actions that are prohibited by local and other anti-corruption laws (collectively “Anti-Corruption Laws”) that may be applicable to one or both parties to the Agreement. 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.

* * *
APPENDIX 1

Clinical trials specific to this permission request are defined below.

Permission has been granted to Licensee, its affiliated companies and subcontractors and research partners, to use the M.I.N.I. 7.0.2 (8/8/16 version), as designated by the terms mentioned above 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:

<table>
<thead>
<tr>
<th>Product / Compound</th>
<th>Study Identification Number / IRB # / ClinicalTrials.gov ID # / Grant #</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>= XXXXX</td>
</tr>
<tr>
<td>Will the M.I.N.I. be done at the screening visit and / or as part of recruitment and / or intake?</td>
<td>Projected number of subjects / patients to be randomized to all treatments / study medications at the baseline visit per protocol / clinical care setting</td>
</tr>
<tr>
<td>Yes / No</td>
<td>= XXXX (Answer 1)</td>
</tr>
<tr>
<td></td>
<td>Projected number of times the M.I.N.I. will be administered to each subject / patient?</td>
</tr>
<tr>
<td></td>
<td>= XXXX (Answer 2)</td>
</tr>
<tr>
<td>A. Research studies only</td>
<td>How many patients do you plan to screen with the M.I.N.I. at the screening visit to get the yield of the number randomized at the end of the baseline visit?</td>
</tr>
<tr>
<td></td>
<td>What is the most accurate way to calculate this number?</td>
</tr>
<tr>
<td></td>
<td>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 M.I.N.I at the beginning of the screening visit to get this yield. This ratio is usually a 2:1 ratio in Major Depressive Disorder or Anxiety Disorder Studies or a 3:1 ratio in schizophrenia studies. This is the best estimate of the number of M.I.N.Is to be done at the screening visit.</td>
</tr>
<tr>
<td></td>
<td>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 M.I.N.I and who still meet eligibility criteria to be randomized to treatment at the end of the baseline visit.</td>
</tr>
<tr>
<td></td>
<td>Given the above information how many patients do you plan to screen with the M.I.N.I at the screening visit to get the yield of the number randomized at the end of the baseline visit?</td>
</tr>
<tr>
<td></td>
<td>= XXXX (Answer 3)</td>
</tr>
</tbody>
</table>
4. Enter required information:

A. For use in research studies only, complete segment A.

B. For use in non-research, clinical settings only, complete segment B.

5. Edit with your name, title, phone, and email.

6. Sign and date.

IN WITNESS WHEREOF the Parties have caused this Agreement to be executed by the hands of their duly appointed representatives on the Effective Date.
Non-Profit settings:

Note: Non-profit institutions sometimes assume that the license fee does not apply because they are “not-for-profit”. This licensing fee applies to all uses that do not meet one of the 3 criteria below.

The following exceptions are granted a “no charge” license fee, but all must first sign a license agreement, and have it approved and counter-signed by Dr. Sheehan:

4. If the study is designed specifically and exclusively to assist refugees or victims of terrorism.

5. If the MINI is used exclusively and only as part of an undergraduate or graduate school research thesis or research dissertation, and not as part of anyone else’s research or data gathering, and the total number of administrations cannot exceed a total of 150 administrations. For this exception to the licensing fee, the student must be the person completing and signing the license agreement. The license is granted to the student for this purpose and not to their institution / mentor / supervisor.

6. If you are a professor using the instrument in the context of directly training students in your class, you are eligible for the “no charge” license to use it in the context of directly training students in your class - as long as it is properly cited and proper copyright attribution is given on any study documents.

For-Profit settings:

The use of the M.I.N.I. Instruments for any “for profit” use, for any gain, or in any “for profit” setting is not free and requires a license agreement signed by the copyright holder and payment of a per use licensing fee. In “for profit” settings or when used for any gain, no part of the M.I.N.I. instruments may be reproduced or transmitted in any form, or by any means, electronic or mechanical, including photocopying, or by any information storage or retrieval system, without written permission from Dr. Sheehan.

The M.I.N.I. Instruments may not be computerized without written permission.
For all permissions contact david sheehan@gmail.com

The key recommended citations for the MINI or MINI Kid are:


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