**APPENDIX B**

**NATIONAL INSTITUTES OF HEALTH**

**NON‑EXCLUSIVE PATENT LICENSE AGREEMENT**

**TO A NIH SOLE CRADA SUBJECT INVENTION FOR INTERNAL RESEARCH USE**

**COVER PAGE**

License Number:

Serial Number(s) of Licensed Patent(s) or Patent Application(s)

of NIH Sole CRADA Subject Invention:

Licensee:

Having an office at:

Cooperative Research and Development Agreement (CRADA) Number:

This Non-Exclusive Internal Research Use Patent License Agreement, hereinafter referred to as the “**Agreement**,” consists of this Cover Page, an attached **Agreement**, and a Signature Page. This **Agreement** is entered into between:

1. The National Institutes of Health (“**NIH**”), an agency within the Department of Health and Human Services, through the Office of Technology Transfer, **NIH**, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852‑3804, U.S.A.; and

2) The party identified above and on the Signature Page (“**Licensee**”).

The **NIH** and the **Licensee** agree as follows:

1. DEFINITIONS
   1. “**Affiliate(s)**” means a corporation or other business entity, which directly or indirectly is controlled by or controls, or is under common control with the **Licensee**. For this purpose, the term "control" shall mean ownership of more than fifty percent (50%) of the voting stock or other ownership interest of the corporation or other business entity, or the power to elect or appoint more than fifty percent (50%) of the members of the governing body of the corporation or other business entity.
   2. “**Government**” means the government of the United States of America.
   3. “**Licensed Patent Rights**” to NIH Sole CRADA Subject Invention shall mean:
      1. U.S. patent applications and patents listed on Cover Page, all divisions and continuations of these applications, all patents issuing from such applications, divisions, and continuations and continuations-in-part that claim the same priority date, foreign counterparts and any reissues, reexaminations, and extensions of all such patents;
      2. **Licensed Patent Rights** shall *not* include one or more claims directed to new matter that is not the subject matter of a claim in 1.3(a).
2. GRANT OF RIGHTS
   1. To the extent the Licensed Patent Rights are solely owned by the U.S. Government as represented by the NIH, the **NIH** hereby grants and the **Licensee** accepts, subject to the terms and conditions of this **Agreement**, a non-exclusive, royalty-free, non-transferable, worldwide license to the **Licensed Patent Rights** to make, have made, and use for internal research purposes only. No rights are granted by NIH to the Licensee to sell, lease, distribute, provide a service, or produce or manufacture products using Licensed Patent Rights.
   2. The **Licensee** has no right to sublicense the Licensed Patent Rights, except that **Licensee** may sublicense to **Affiliates**, and **Licensee** may sublicense to academic institutions, non-profits, and contractors for the sole purpose of supporting **Licensee**’s internal research under this **Agreement**.
   3. This **Agreement** confers no license or rights or any waiver of rights by implication, estoppel, or otherwise under any patent applications or patents of the **NIH** other than the **Licensed Patent Rights,** regardless of whether such patents are dominant or subordinate to the **Licensed Patent Rights**.
3. PERFORMANCE
   1. The **Licensee** agrees not to use the **Licensed Patent Rights** for research involving human subjects or clinical trials in the United States without complying with [21 C.F.R. Part 50](http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr50_02.html) and [45 C.F.R. Part 46](http://www.access.gpo.gov/nara/cfr/waisidx_03/45cfr46_03.html).
4. NEGATION OF WARRANTIES
   1. THE **NIH** MAKES NO WARRANTIES OF ANY KIND, EXPRESSED OR IMPLIED, INCLUDING OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE LICENSED PATENT RIGHTS, INCLUDING ANY SUBJECT MATTER DEFINED BY THE CLAIMS OF THE **LICENSED PATENT RIGHTS**. The **NIH** does not warrant the validity of the **Licensed Patent Rights** and makes no representations whatsoever with regard to the scope of the **Licensed Patent Rights** or that the **Licensed Patent Rights** may be exploited without infringing other patents or other intellectual property rights of third parties or of the NIH.
5. TERM, TERMINATION AND MODIFICATION OF RIGHTS
   1. This **Agreement** is effective when signed by both parties.
   2. The **Licensee** shall have a unilateral right to terminate this **Agreement** by giving the **NIH** written notice to that effect. The **NIH** shall have a unilateral right to terminate this **Agreement** only if **Licensee** is found to be in material breach of this **Agreement** by giving the **Licensee** thirty (30) days written notice to that effect.
   3. If either party desires a modification to this **Agreement**, the parties shall, upon reasonable notice of the proposed modification by the party desiring the change, confer in good faith to determine the desirability of the modification. No modification shall be effective until a written amendment is signed by both parties to this **Agreement.**
   4. Paragraphs 4.1 and 5.2-5.4 of this **Agreement** shall survive termination of this **Agreement**.
6. GENERAL PROVISIONS
   1. This **Agreement** constitutes the entire agreement between the parties relating to the subject matter of the **Licensed Patent Rights** and all prior negotiations, representations, agreements, and understandings are merged into, extinguished by, and completely expressed by this **Agreement**.
   2. The provisions of this **Agreement** are severable and in the event that any provision of this **Agreement** shall be determined to be invalid or unenforceable under any controlling body of law, such determination shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.
   3. The construction, validity, performance, and effect of this **Agreement** shall be governed by Federal law as applied by the Federal courts in the District of Columbia.
   4. All **Agreement** notices required or permitted by this **Agreement** shall be sent by email to the contact designated on the Signature Page. Notices shall be effective as of the date of the receipt of such notice.
   5. This **Agreement** shall not be assigned or otherwise transferred (including any transfer by legal process or by operation of law, and any transfer in bankruptcy or insolvency, or in any other compulsory procedure or order of court) except to the **Licensee’s** **Affiliate(s)** without the prior written consent of the **NIH**. The parties agree that the identity of the parties is material to the formation of this **Agreement** and that the obligations under this **Agreement** are nondelegable.
   6. The parties agree to attempt to settle amicably any controversy or claim arising under this **Agreement** or a breach of this **Agreement**, except for appeals of modification or termination decisions provided for in Article 5. The **Licensee** agrees first to appeal any such unsettled claims or controversies to the designated **NIH** official or designee, whose decision shall be considered the final agency decision. Thereafter, the **Licensee** may exercise any administrative or judicial remedies that may be available.
   7. The terms and conditions of this **Agreement** shall, at the **NIH’s** sole option, be considered by the **NIH** to be withdrawnfrom the **Licensee’s** consideration and the terms and conditions of this **Agreement**,and the **Agreement** itself, to be null and void,unless this **Agreement** is executedby the **Licensee** and a fully executed original is received by the **NIH**.

**SIGNATURES BEGIN ON NEXT PAGE**

**SIGNATURE PAGE**

In Witness Whereof, the parties have executed this **Nonexclusive Internal-Use Patent License Agreement** on the dates set forth below.

FOR **NIH**:

by:

Richard U. Rodriguez Date

Director, Division of Technology Development and Transfer

Office of Technology Transfer

National Institutes of Health

Email: [rodrigr@mail.nih.gov](mailto:rodrigr@mail.nih.gov)

For the **Licensee**:

by:

Signature of Authorized Official

Name Date

Title

Address

Email: