MATERIALS COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT WITH THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

This Materials Cooperative Research and Development Agreement ("MCRADA" or "Agreement") is entered into by and between Lexogen GmbH, which has its principal place of business at Campus Vienna Biocenter 5, 1030 Vienna, Austria ("the Collaborator"), and the Center for Computational Toxicology and Exposure ("the Center"), of the U.S. Environmental Protection Agency ("EPA") under the authority of Title 15, United States Code §§ 3710a-3710d (commonly known as the Federal Technology Transfer Act of 1986).

This Materials Cooperative Research and Development Agreement ("Materials CRADA") has been adopted for use by the EPA for collaborations that will not exceed two years in term; will involve transfers of essential material ("Research Material"), but no other resources; and are unlikely to result in new intellectual property. Typical applications include short-term studies to: 1) test new reagents or research tools when such assessments require collaboration between provider and recipient institutions; or 2) determine the feasibility, optimal study design, and/or resource requirements for a long-term study between the collaborating institutions. Collaborative research and development studies not meeting these criteria must be submitted for approval using the standard CRADA agreement.

1. Determination of Provider and Recipient

IF COLLABORATOR IS THE PROVIDER
Lexogen GmbH, PROVIDER, agrees to transfer to the EPA, RECIPIENT, the following Research Material:

Material	**QTY**
CORALL RNA-Seq Library Prep Kit, with universal dual indices ("UDIs") V2, 96 reactions (SR9037.96)	1 kit
Poly(A) RNA Selection Kit V1.5	1 kit
CORALL RNA-Seq Library Prep Kit, with UDIs V2 User Guide (SR9037UG228V0100) User information for use of control RNA (SR9037UI340V0100) Control RNA in 24-well plate format for 8 reactions, UHRR, dried.	8 wells

This Materials CRADA involves no other exchange of personnel or resources. This Agreement is made under authority of the Federal Technology Transfer Act, 15 U.S.C. § 3710a.

2. If the data or material that are being transferred constitute human subjects research, please visit the following intranet site to determine if your project needs review and approval by the HSRRO: http://intranet.ord.epa.gov/p2/hsr/human-subjects-review

Does the research involve specimens or data derived or collected from human subjects?

☑ No
☐ Yes – I am seeking review and approval from the HSSRO.

3. If the data or material that are being transferred involve life sciences research or more specifically, any of the select agents or toxins listed and/or the definitions provided in EPA Order 1000.19 *Policy and Procedures for Managing Dual Use Research of Concern*, then Principal Investigators should consult EPA's Institutional Contact for Dual Use Research of Concern (ICDUR) at DURC@epa.gov before completing the following section. If not, then check the first box below.

☑ This research does not meet any of the definitions of Dual Use Research of Concern (DURC) and no additional review or oversight are required. The PI must report to the ICDUR any results or changes in the research that meet any of the definitions of DURC.

☐ This research meets one or more definitions of DURC and requires additional oversight under the *USG Policy for Institutional Oversight of DURC*. The parties to this Agreement are required to comply with EPA Order 1000.19, *Policy and Procedures for Managing Dual Use Research of Concern.*

For information about DURC and EPA Order 1000.19, please visit: http://intranet.ord.epa.gov/homeland-security/dual-use-research-concern-durc-policies

4. To the extent permitted by law, each Party agrees to treat as confidential any of the disclosing Party's written information about this Research Material that is stamped "CONFIDENTIAL" for a period of three (3) years from the date of the disclosure. The foregoing shall not apply to information that is or becomes publicly available or which is disclosed to a Party without a confidentiality obligation. Any oral disclosures by either party that the disclosing Party wishes to be treated as confidential shall be identified as being confidential at the time of disclosure and by written notice delivered to the receiving Party within (10) days of the oral disclosure. The Center may publish or otherwise publicly disclose the results of the Research Plan, but if Collaborator has given CONFIDENTIAL information to the Center, such public disclosure may be made only after Collaborator has had thirty (30) days to review the proposed disclosure to determine if it contains any CONFIDENTIAL information, to the extent such review period is permitted by law.

5. The RECIPIENT agrees to retain control over this Research Material, and further agrees not to transfer the Research Material to any person outside of the Molecular Indicators Branch ("MIB"), within the Center, without advance written approval of the PROVIDER. The PROVIDER reserves the right to distribute the Research Material to others and to use it for its own purposes. When the Research Plan is completed or one (1) year has elapsed, whichever occurs

first, or the Materials CRADA is terminated, the RECIPIENT will dispose of the Research Material as directed by the PROVIDER.

6. This Research Material is provided as a service to the research community. IT IS BEING SUPPLIED TO THE RECIPIENT WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. The PROVIDER makes no representations that the use of the Research Material will not infringe any patent or proprietary rights of third parties. The PROVIDER shall not be liable for any claims or damages arising from the RECIPIENT'S use of the Research Material; however, no indemnification is provided or intended.

7. The Center and the Collaborator believe that no Subject Inventions or Computer Software will be created during the work specified in this Agreement. Should it appear that any activity of this Agreement might involve the creation of Subject Inventions or Computer Software, the Center and the Collaborator will negotiate a standard CRADA in good faith. The standard CRADA will assign responsibilities for obtaining patents or other intellectual property rights pertaining to the Subject Inventions or Computer Software and will provide for appropriate allocation of any patent or intellectual property rights resulting from those Subject Inventions or Computer Software. Subject Invention means any invention, conceived, or first actually reduced to practice in the performance of this Agreement. Computer Software means computer software, computer programs, computer data bases, and documentation thereof developed, in whole or in part, under this Agreement.

8. Any dispute arising under this Agreement which cannot be readily resolved shall be submitted jointly to the signatories of this Agreement. A joint decision of the signatories or their designees shall be the disposition of such dispute. If the signatories are unable to jointly resolve a dispute within a reasonable period of time after submission of the dispute for resolution, the matter shall be submitted **by EPA** to the Administrator of EPA or the Administrator's designee for resolution.

9. The illegality or invalidity of any provisions of this Materials CRADA shall not impair, affect, or invalidate the other provisions of this Materials CRADA.

10. Neither this Materials CRADA nor any rights or obligations of any Party hereunder shall be assigned or otherwise transferred by either Party without the prior written consent of the other Party.

11. All notices pertaining to or required by this Agreement shall be in writing and shall be signed by an authorized representative and shall be delivered by hand (including private courier mail service) or sent by certified mail, return receipt requested, with postage prepaid, addressed as follows:

IF TO THE COLLABORATOR:
Stephane Barges, CEO, Lexogen GmbH
Campus Vienna Biocenter 5

1030 Vienna, AUSTRIA
+43(0) 1 345 1212-32
stephane.barges@lexogen.com

With a copy to:
Lena Nagy, CFO, Lexogen GmbH
Campus Vienna Biocenter 5
1030 Vienna, AUSTRIA
+43(0) 1 345 1212-31
lena.nagy@lexogen.com

IF TO THE CENTER:
Russell Thomas
Center for Computational Toxicology and Exposure (CCTE)
109 TW Alexander (MD-B-205-01)
Research Triangle Park, NC 27711
919-541-5776
thomas.russell@epa.gov

With a copy to:
Samantha Plishka
Center for Computational Toxicology and Exposure (CCTE)
109 TW Alexander (AA005)
Research Triangle Park, NC 27711
919-541-2657
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AND

Adam Biales
Center for Computational Toxicology and Exposure (CCTE)
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biales.adam@epa.gov

AND

Kathleen Graham
FTTA Program Coordinator
graham.kathleen@epa.gov
(303) 312-6137
ftta@epa.gov

Any party may change such address by notice given to the other party in the manner set forth above.

12. By entering into this Materials CRADA, the Center does not directly or indirectly endorse any product or service provided, or to be provided, whether directly or indirectly related to either this Materials CRADA or to any patent or other intellectual property license or agreement which is related to this Materials CRADA. The Collaborator shall not in any way state or imply that this Materials CRADA is an endorsement by the U.S. Government or any of its organizational units or employees of any such product or service. Any statements, including promotional materials, prepared by the Collaborator that describe this Materials CRADA must be approved in advance by the EPA.

13. Either the Center or the Collaborator may unilaterally terminate this entire Agreement at any time by giving written notice to the other party at least thirty (30) days prior to the desired termination date.

14. This Materials CRADA constitutes the entire agreement between the Parties and supersedes any prior understanding or written or oral agreement.

15. This Materials CRADA shall be construed in accordance with Federal law as applied by the Federal courts in the District of Columbia.

16. The undersigned expressly certify and affirm that the contents of any respective statements made or reflected in this Materials CRADA are truthful and accurate and that the signatories hereto have the authority to bind their respective organizations to this agreement.

17. This Materials CRADA shall be effective upon execution by the Parties when the last signatory has signed the document. The term of this Materials CRADA is twelve (12) months from execution.

18. The provisions of Articles 3, 4, 5, 6, 9, 12 and 15 shall survive the termination of this Materials CRADA.

THE CENTER

By: [redacted] Date _____

THE COLLABORATOR

B [redacted]

APPENDIX A

RESEARCH PLAN

Research Plan to test the Materials as follows:

1. EPA will prepare eight (8) control reactions using the Control RNA provided by Lexogen as described in CORALL RNA-Seq Library Prep Kit, with UDIs V2 User Guide (SR9037UG228V0100) and User information for use of control RNA (SR9037UI340V0100). EPA will then either:

    a) provide the sequencing data for these eight (8) samples obtained on site to Lexogen; **or**

    b) return the prepared libraries to Lexogen for sequencing. If returned to Lexogen, Lexogen agrees to provide EPA the sequencing data it obtains.

2. EPA will provide feedback to Lexogen regarding the CORALL RNA-Seq Library Prep Kit V2, 96 reactions (SR9037.96) with UDIs:

- Through written and/or verbal communications, in a form agreed to by the Parties; and

- As per the terms of Paragraph 12 of this Agreement, Lexogen will seek the Center's permission if the Center's feedback is intended to be used publicly by Lexogen (e.g., in a quote or commercial testimonial).