EPA – InSCREENex – MTA #1225-19 Date: 5/31/2019

MATERIALS TRANSFER AGREEMENT

Provider: InSCREENeX GmgH
Provider Contact (not signator)
Name: Tobias May
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Phone: +49 531 6181 5080
Email: tobias.may@inscreenex.com

Recipient: U.S. Environmental Protection Agency (EPA)
Office of Research and Development (ORD)
National Center for Computational Toxicology (NCCT)
Recipient Contact (not signator)
Name: Chad Deisenroth, Ph.D.
Address: ORD/NCCT 109 T.W. Alexander Dr, (D143-02), RTP, NC 27711
Phone: 919-541-4219
Email: Deisenroth.chad@epa.gov

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1. Provider agrees to transfer to Recipient the following Research Material:

Selected clonal variants of immortalized human thyroid epithelial cells, huThyrECs (INS-CI-1017)

2. This Research Material may not be used in human subjects. The Research Material will be used only for research purposes by Recipient's investigator in his/her laboratory, for the research project described below, under suitable containment conditions. This Research Material will not be used for screening, production or sale, for which a commercialization license may be required. Recipient agrees to comply with all Federal rules and regulations applicable to the Research Project and the handling of the Research Material.

EPA ONLY: 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

X There is no Human Subjects material being used in this research.

□ Research Plan reviewed and approval by HSRRO:
Name _____ Date __/__/____

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

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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.

X 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. This Research Material will be used by Recipient's investigator solely in connection with the following research project ("Research Project") described with specificity as follows:

The Food Quality Protection Act directs the Agency to test chemicals for potential endocrine disrupting effects. In response, the EPA established the Endocrine Disruptor Screening Program (EDSP) to evaluate chemicals for effects on the endocrine system, including the thyroid. There are currently no in vitro assays in the EDSP to evaluate the effects of chemical exposures on thyroid hormone production in a human model system. To address this need, we have developed an in vitro organotypic culture model of the human thyroid that can be utilized for assessing the disruptive effects of chemicals on thyroid hormone synthesis (QAPP A-IO-0030763).

A significant challenge for this project has been sourcing high-quality, human-derived, primary thyroid cells for assay development and screening. The objective of this research project is to evaluate a number of clonal variants of a single human immortalized thyrocyte line developed by InSCREENeX for structural and functional phenotypes that can recapitulate the primary cell model system. If clonal variant(s) are identified that faithfully reproduce the effects of the current model, it could significantly accelerate the timing and expand the scope for high-priority thyroid-related screening activities planned within the Agency. In addition, the use of immortalized cells would enable a renewable source of cells that would provide greater consistency to hazard identification efforts at a significantly reduced cost.

5. In all oral presentations or written publications concerning the Research Project, Recipient will acknowledge Provider's contribution of this Research Material unless requested otherwise. To the extent permitted by law, Recipient agrees to treat as confidential, any of Provider's written information about this Research Material that is stamped "CONFIDENTIAL" for a period of three (3) years from the date of its disclosure to recipient. The foregoing shall not apply to information that is or becomes publicly available or which is disclosed to Recipient without a confidentiality

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obligation. Any oral disclosures from Provider to Recipient, which Provider wishes to be treated as confidential, shall be identified as being Confidential at the time of the disclosure and by written notice delivered to Recipient within thirty (30) days after the date of the oral disclosure. Recipient may publish or otherwise publicly disclose the results of the Research Project, but if Provider has given Confidential information to Recipient, such public disclosure may be made only after Provider has had thirty (30) days to review the proposed disclosure to determine if it includes any Confidential information, to the extent such review period is permitted by law.

6. This Research Material represents a significant investment on the part of Provider and is considered proprietary to Provider. Recipient's investigator therefore agrees to retain control over this Research Material and further agrees not to transfer the Research Material to other people not under his/her direct supervision without advance written approval of Provider. Provider reserves the right to distribute the Research Material to others and to use it for its own purposes. When the Research Project is completed, the Research Material will be returned to the Provider or disposed, if directed by Provider.

7. This Research Material is provided as a service to the research community. It is being supplied to Recipient with no warranties, express or implied, including any warranty of merchantability or fitness for a particular purpose. Provider makes no representations that the use of the Research Material will not infringe any patent or proprietary rights of third parties.

8. Recipient shall retain title to any patent or other intellectual property rights in inventions made by its employees in the course of the Research Project. However, if said inventions contain any portion of the Research Material are derived from the Research Material, or could not have been produced but for the use of the Research Material, Recipient agrees to contact the Provider to determine what ownership interests, if any, the Provider may have, and, where applicable, to negotiate in good faith the terms of a commercial license. Inventorship for a patent application or a commercialized product based on said inventions shall be determined according to United States patent law.

9. When Provider is the EPA: Recipient agrees not to claim, infer, or imply endorsement by the Government of the United States of America (hereinafter referred to as "Government") of the Research Project, the institution, or personnel conducting the Research Project or any resulting product(s). Recipient agrees to hold the Government harmless and to indemnify the Government for all liabilities, demands, damages, expenses, and losses arising out of Recipient's use for any purpose of the Research Material.

10. When Recipient is the EPA: Provider will not be liable to EPA for any claims or damages arising from EPA's use of the Research Material.

11. The Provider shall have the right to terminate this Agreement at any time if Recipient breaches any of the terms of this Agreement. Upon termination, Recipient shall return to the Provider all unused portions of the Research Materials.

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12. Will EPA develop any products or services from information or materials provided by the Recipient?

__X__ Yes – go to item A

____ No – skip to #13 (next clause)

Item A: The EPA laboratory must coordinate on matters related to Quality Assurance with their QA Specialist.

__X___ If necessary, the Laboratory will develop/has developed a Quality Assurance Plan in coordination with the Quality Assurance Specialist. (QAPP A-IO-0030763 for more information)

_____ No QA requirements are needed.

13. 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:

Provider's Contact Information:

InSCREENeX GmgH
Name: Tobias May
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Phone: +49 531 6181 5080
Email: tobias.may@inscreenex.com

Recipient's Contact Information:

US EPA
Name: Chad Deisenroth, Ph.D.
Address: ORD/NCCT 109 T.W. Alexander Dr, (D143-02), RTP, NC 27711
Phone: 919-541-4219
Email: Deisenroth.chad@epa.gov

With a copy to:
Kathleen Graham
FTTA Program Coordinator
Graham.kathleen@epa.gov

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