EPA – BfR – MTA # 1479-22 Date: 08/10/2022

MATERIALS TRANSFER AGREEMENT

Provider: EPA National Center for Computational Toxicology and Exposure (CCTE)
Provider Contact (not signator)
Name: Joshua A. Harrill
Address: 109 TW Alexander Drive, Research Triangle Park, NC 27709
Phone: 1-919-260-5294
Email: Harrill.Joshua@epa.gov

Recipient: German Federal Institute for Risk Assessment (BfR)
Recipient Contact (not signator)
Name: Dr. Shu Liu
Address: Diedersdorfer Weg 1, D-12277 Berlin, Germany
Phone: +49 30 18412 29307
Email: Shu.Liu@bfr.bund.de

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

Aliquots of Dimethyl Sulphoxide (DMSO) solubilized chemicals from the Tox21 Cross Partner Project #5 (CPP5) set, consisting of 315 chemicals. The volumes of DMSO solubilized CPP5 chemicals to be provided by CCTE will be decided in cooperation with BfR but will not exceed 100 microliters (uL) per chemical.

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 Center, 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: https://intranet.ord.epa.gov/human-subject-research/hsr-projects-review

☒ 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 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. 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:

Recipient will use the Research Material for modified Cell Painting and iterative indirect immunofluorescence imaging (4i) screening in several immortalized cell lines (U2OS, MCF-7, A549, HepG2, HCT116, LUHMES, and RPTEC). Recipient will also use the Research Material in screenings with several transgenic reporter cell lines expressing tumor suppressors or oncogenic proteins for cancer prediction. Recipient intends to identify bioimaging-based patterns for compounds that have (organ) specific, toxic effects and to develop pattern-based prediction models for the reliable identification of compound-specific hazards relevant to regulatory risk assessment.

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. No information claimed as confidential business information by either party to this Agreement or by any third party shall be shared between PROVIDER and RECIPIENT under the terms of this Agreement.

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, to the extent such destruction is permitted by law.

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.

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

____ Yes – go to item A

_X_ No – skip to #13 (next clause)

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

☐ If necessary, the Center will develop/has developed a Quality Assurance Plan in

coordination with the Quality Assurance Specialist.

☒ 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:

Russell Thomas
U.S. EPA Center for Computational Toxicology and Exposure (CCTE)
109 T.W. Alexander (MD-D143-02)
Research Triangle Park, NC 27711
919-541-5776
thomas.russell@epa.gov

With a copy to:
Samantha Plishka
U.S. EPA Center for Computational Toxicology and Exposure
109 T.W. Alexander
Research Triangle Park, NC 27711
919-541-2657
Plishka.Samantha@epa.gov

For commercial courier address use:
4930 Old Page Road
Durham, NC 27703

AND

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

Recipient's Contact Information:
Dr. Shu Liu
German Federal Institute for Risk Assessment
Unit "Strategies for Toxicological Assessments"

Department "Experimental Toxicology and ZEBET"
Diedersdorfer Weg 1
D-12277 Berlin, Germany
Phone: +49 30 18412 29307
Email: Shu.Liu@bfr.bund.de

With a copy to:
Prof. Dr. Gilbert Schönfelder
German Federal Institute for Risk Assessment
Head of Department "Experimental Toxicology and ZEBET"
PO Box: 12 69 42
D-10609 Berlin; Germany
Phone: +49 30 18412 29000
Email: gilbert.schoenfelder@bfr.bund.de

14. Paragraphs 2, 5, 7, 8, 9, and 10 shall survive termination.

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

16. The undersigned Provider and Recipient expressly certify and affirm that the contents of any statements made herein are truthful and accurate.

17. This agreement shall enter into force as of the date of the last signature of the parties and shall remain in effect for one year from said date.

Authorized Representative of Institution SIGNATURES

FOR THE RECIPIENT

[redacted]

FOR THE PROVIDER

[redacted]