UC Berkeley – EPA MTA #

Date Last Saved: January 19, 2012

MATERIALS TRANSFER AGREEMENT

Provider:

U.S. Environmental Protection Agency (EPA)
Office of Research and Development (ORD)
National Center for Computational Toxicology (NCCT)

Recipient:
Regents of the
University of California at Berkeley Campus

1. Provider agrees to transfer to Recipient's Investigator named below the following Research Material:

ToxCast chemicals and reagents

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.

3. Does the Research Material include specimens or data derived or collected from human subjects?
_____ Yes – Go to item #3(a).
__X___ No – Skip to item #4.

3(a). Does the Research Material include specimens or data derived or collected from fetuses, children, pregnant women, or nursing women?
_____ Yes
_____ No

3(b). Was the Research Material obtained under a protocol that was reviewed and approved by an Institutional Review Board (IRB) that operated in accordance with the requirements of EPA Regulation 40 CFR 26, HHS Regulation 45 CFR 46, or any other Federal Regulation for the protection of human research subjects?
_____ Yes (Please indicate the applicable Regulation here _____ and provide copies of the protocol and IRB approval documents.)
_____ No (Please provide explanation with documentary support as appropriate.)

3(c). Can the Provider of the Research Material identify the subjects directly or through identifiers (codes) linked to the subjects?
_____ Yes – The Recipient's use of the Research Material may be human subjects research subject to 40 CFR 26. Go to item #3(d).
_____ No – The Recipient's use of the Research Material is not human subjects research subject to 40 CFR 26. Skip to item #4.

3(d). Is the Provider of the Research Material prohibited by this agreement from releasing information to the Recipient that might allow the identification of any of the subjects, including but not limited to the key to any existing code?
_____ Yes – The Recipient's use of the Research Material is not human subjects research subject to 40 CFR 26. Skip to item #4.
_____ No – The Recipient's use of the Research Material may be human subjects research subject to 40 CFR 26. Go to item #3(e).

3(e). Is the Research Material publicly available?
_____ Yes – The Recipient's use of the Research Material is human subjects research that is exempt from 40 CFR 26.
_____ No – The Recipient's use of the Research Material is human subjects research that may be subject to 40 CFR 26 and must be further evaluated accordingly by the EPA Human Subjects Review Official.

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 ***(insert description here or use an attachment page if necessary)***:

SUMMARY: The "Recipient" shall use an automated high-throughput method to screen the yeast knockout collection for deletion mutants that exhibit sensitivity or resistance to ToxCast chemicals selected by mutual agreement. Computational and confirmatory analyses, along with comparisons to existing ToxCast data, will provide information on the cellular processes and pathways affected by these compounds.

AIM 1: Perform automated high-throughput screens of the yeast deletion collection to identify mutants that are sensitive or resistant to potential genotoxic ToxCast compounds.

"Recipient" shall simultaneously assess the growth of a pool of ~4600 non-essential yeast gene deletion strains exposed to a toxicant. "Recipient" shall utilize the toxicant exposure strategy [homozygous deletion pools grown for 5 and 15 generations after each toxicant exposure at three doses (the IC_{20}, 50% IC_{20} and 25% IC_{20}) that has been used successfully previously to identify susceptible yeast strains. "Recipient" shall utilize high throughput sequencing of the unique DNA barcodes which identifies each deletion strain to quantitate the relative growth of

each strain in the different exposures. "Recipient" shall identify and rank deletions strains based on their relative sensitivity or resistance to each toxicant.

AIM 2: Confirm selected cellular processes and pathways as affected by each of the tested ToxCast compounds using individual comparative growth analysis of selected deletion strains.

"Recipient" shall select representative ~10 deletion strains which show differential sensitivity to each toxicant for confirmatory dose response analysis. "Recipient" shall use flow cytometry based approach that quantifies the growth of each deletion strain in comparison to wild type in the presence of toxicant.

AIM 3: Integrating functional data to provide insight on mode of action.

"Recipient" shall utilize the functional data to infer mode of action or each toxicant. Existing data on multiple toxicants as well as new data generated in this project shall be incorporated into this analysis. "Recipient" shall collaborate with "Provider" to assist in comparison of the data sets. The combination of data provides important information on the specificity of the molecular response for each chemical and helps identify both the shared and unique molecular responses to toxicant exposure.

Outcome: Anticipation of identifying the functional processes that are required in yeast after exposure to the tested compounds and provide insight into their modes of action.

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 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.

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 has a long history of applying principles of quality assurance/quality control to all technical work conducted by or for the Agency (CIO 2106: USEPA Quality Policy). Given EPA is receiving (***fill-in information/material***) and will use the (***fill-in information/material***) for Agency purposes, the Recipient is required to provide EPA with documentation such as a quality manual, describing their organization's quality system. Documentation showing third party accreditation to a relevant standard and scope is also acceptable for documenting an organization's quality system. EPA requirements for quality management plans can be found at this URL: http://www.epa.gov/quality/qa_docs.html

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:

John Southerland
Extramural Specialist

National Center for Computational Toxicology (NCCT)
US EPA
109 TW Alexander (MD-B-205-01)
Research Triangle Park, NC 27711

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

919-541-3416
southerland.john@epa.gov

Recipient's Contact Information:

Kevin Christopher
Industry Alliances Office

University of California, Berkeley
2150 Shattuck Ave., Suite 950
Berkeley, CA 94704-6701

510-642-5829
kchristopher@berkeley.edu

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

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

16. 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.