MATERIALS TRANSFER AGREEMENT

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

and

Institute of Occupational Medicine (IOM)
Riccarton, Edinburgh EH14 4AP
United Kingdom

1. **EPA agrees**:

1) To receive up to 10 selected reference materials provided by IOM or other consortia collaborators who are affiliated with the project.
2) To conduct in vitro testing of these nanomaterials in appropriate assays that are part of the ToxCast™ and Tox21 Chemical Prioritization Programs. Materials and assays will be selected based on compatibility of materials and assay methods. The selections of materials and methods will be a joint decision of the EPA and IOM principals.
3) To evaluate the bioactivity profiles of the tested nanomaterials using ToxCast™ and Tox21 algorithms to predict potential in vivo toxicities.
4) The nanomaterials are the property of IOM and all existing rights including, without limitation, patent rights in or to the nanomaterials will remain the property of the IOM or its provider (as appropriate.)
5) The nanomaterials will be used with caution and for research purposes only, and shall not be used for research involving human subjects.
6) All data resulting from the testing of the nanomaterials in the ToxCast™ and Tox21 Programs will be provided to IOM.
7) All data will be used only by the EPA in the ToxCast™ and Tox21 Programs described below, under suitable containment conditions.
8) All data will not be used for screening, production or sale, for which a commercialization license may be required.

IOM agrees:

1) To provide up to 10 selected reference materials to the EPA, or ensure that the appropriate ENPRA Project Affiliates provide the selected materials to EPA.
2) To provide appropriate physico-chemical characterization data for materials supplied.
3) To receive all data resulting from the testing of the nanomaterials in the ToxCast™ and Tox21 programs. Materials and assays will be selected based on compatibility

of materials and assay methods. The selections of materials and methods will be a joint decision of the EPA and IOM principals.

4) All data will be used only by IOM for use in the ENPRA project.

Both IOM and EPA agree to comply with all applicable laws, rules, guidelines and regulations applicable to the use, storage, shipping and the handling of the nanomaterials and ToxCast™ and Tox21 Programs.

2. EPA's 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. Recipient agrees to comply with all Federal rules and regulations applicable to the Research Project and the handling of the Research Material.

3. The EPA Research Material does not include specimens or data derived or collected from human subjects.

4. The EPA Research Material will be used by Recipient's investigator solely in connection with the following research projects described with specificity as follows

IOM and EPA will partner on a project for the European Commission titled "Risk Assessment of Engineered Nanoparticles" (ENPRA) (the "Project"). The IOM is a member of a consortium examining computational models that will complement and extend the QSAR approach. EPA is engaged in research and development work in the field of health and safety issues regarding nanotechnology and has an ongoing comprehensive chemical screening research program called ToxCast™ that is testing thousands of chemicals in bioassays for predictive toxicity and chemical prioritization, and the EPA is an active participant in the U.S. Government's Tox21 consortium to transform the field of toxicology to a more predictive science. IOM and the EPA have complementary expertise and this collaboration will bring a wide variety of expertise to bear on the rapidly emerging issue of development of effective risk assessment strategies for nanomaterials.

5. In all oral presentations or written publications concerning the ToxCast™ and Tox21 Programs, EPA will acknowledge IOM's contribution of the IOM nanomaterials unless requested otherwise by IOM. To the extent permitted by law, EPA agrees to treat as confidential, any of IOM's written information about the IOM nanomaterials that is stamped "CONFIDENTIAL." The foregoing shall not apply to information that is or becomes publicly available or which is disclosed to EPA without a confidentiality obligation. Any oral disclosures from IOM to EPA which IOM wishes to be treated as confidential shall be identified as being Confidential at the time of the disclosure and by written notice delivered to EPA within thirty (30) days after the date of the oral disclosure. EPA may publish or otherwise publicly disclose the results of the ToxCast™

and Tox21 Programs, but if IOM has given Confidential information to EPA, such public disclosure may be made only after IOM has had sixty (60) days to review and comment on the proposed disclosure to determine if it includes any Confidential information, to the extent such review period is permitted by law.

6. The EPA will provide to IOM in writing all results and conclusions of any research obtained by the EPA utilizing the IOM nanomaterials in the ToxCast™ and Tox21 Programs, and EPA will not use those results and conclusions to file any patent applications that claim the manufacture, use or sale of the IOM nanomaterials.

Both parties grant to each other a non-exclusive license to use the results of the ToxCast™ and Tox21 Programs using the IOM nanomaterials in their own research.

Both parties acknowledge that such testing results shall be made freely available to the public following the review process described in section 5 above.

7. Are Testing Results being provided back to EPA that include specimens or data derived or collected from human subjects?
_____ Yes – Go to item #7(a).
__X___ No – Skip to item #8.

7(a). Do these Testing Results include specimens or data derived or collected from fetuses, children, pregnant women, or nursing women?
_____ Yes
_____ No

7(b). Were these Testing Results 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.)

7(c). Can the Provider of the Testing Results identify the subjects directly or through identifiers (codes) linked to the subjects?
_____ Yes – EPA's use of the Research Material may be human subjects research subject to 40 CFR 26. Go to item #7(d).
_____ No – EPA's use of the Research Material is not human subjects research subject to 40 CFR 26. Skip to item #8.

7(d). Is the Provider of the Testing Results prohibited by this agreement from releasing information to the EPA that might allow the identification of any of the subjects, including but not limited to the key to any existing code?
_____ Yes – EPA's use of the Research Material is not human subjects research subject to 40 CFR 26. Skip to item #8.
_____ No – EPA's use of the Research Material may be human subjects research subject to 40 CFR 26. Go to item #7(e).

7(e). Is the Research Material publicly available?
_____ Yes – EPA's use of the Research Material is human subjects research that is exempt from 40 CFR 26.
_____ No – EPA'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.

8. The IOM nanomaterials represent a significant investment on the part of IOM and are considered proprietary to IOM. The EPA therefore agrees to retain control over the IOM nanomaterials and further agrees not to transfer the IOM nanomaterials to other people or parties without advance written approval of IOM. IOM reserves the right to distribute the IOM nanomaterials to others and to use it for its own purposes.

9. The ToxCast™ and Tox21 Programs and the IOM nanomaterials are provided as a service to the research community. They are being supplied "as is" with no representations, warranties, express or implied, of any kind, including any warranty of merchantability or fitness for a particular purpose. Neither party makes any representations that the use of the ToxCast™ and Tox21 Programs or IOM nanomaterials will not infringe any patent or proprietary rights of third parties.

10. EPA shall retain title to any patent or other intellectual property rights in inventions made by its employees in the course of the performance of the ToxCast™ and Tox21 Programs. However, notwithstanding Section 6, above, if said inventions contain any portion of the IOM nanomaterials, are derived from the IOM nanomaterials, or could not have been produced but for the use of the IOM nanomaterials, the EPA agrees to contact IOM to determine what ownership interests, if any, IOM 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. Neither this letter agreement nor the performance of it by EPA will transfer to EPA any proprietary right, title, interest or claim in or to any of the IOM nanomaterials (including any intellectual property rights subsisting therein).

11. IOM agrees not to claim, infer, or imply endorsement by the Government of the United States of America (hereinafter referred to as "Government") or the ToxCast™ and Tox21 Programs, the institution or personnel conducting the ToxCast™ and Tox21 Programs or any resulting product(s).

12. Either party shall have the right to terminate this Agreement at any time. Upon termination, the performance of the ToxCast™ and Tox21 Programs using the IOM nanomaterials shall end, and the EPA shall return to IOM all unused portions of the IOM nanomaterials.

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:

EPA's Official and Mailing Address:

Keith Houck or Monica Linnenbrink
US EPA/ORD/NCCT
109 TW Alexander Dr, MD-B-205-01
Research Triangle Park, NC 27711
Linnnenbrink.monica@epa.gov
Houck.Keith@epa.gov
919-541-4219

IOM's Official and Mailing Address:

Lang Tran
Institute of Occupational Medicine
Riccarton, Edinburgh EH14 4AP
United Kingdom
susan.scarisbrick@iom-world.org

14. Paragraphs , 9, 11 and 12 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. Will EPA develop any products or services from information or materials provided by the Recipient?

____ Yes – go to item A

____ No – skip to (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 (see CIO 2106: USEPA Quality Policy). Given EPA is receiving Testing Results and will use the Testing Results for Agency purposes, the Recipient is required to provide EPA with documentation, such as a quality manual, describing their organization's quality system. A copy of a certificate of registration showing current third party accreditation to ISO 17025 in the field of testing being applied to the Research Materials shall be considered acceptable for documenting an organization's quality system. Standard operating procedures used for generating Testing Results shall be appended to the quality system documentation. EPA requirements for quality management plans can be found at this URL: http://www.epa.gov/quality/qa_docs.html The adequacy of the quality system is a critical deciding factor in approval of this MTA by EPA.