ANNEX 2

NATIONAL CANCER INSTITUTE
NANOTECHNOLOGY CHARACTERIZATION LABORATORY
MATERIAL TRANSFER AGREEMENT

The National Cancer Institute (NCI) Nanotechnology Characterization Laboratory (NCL) has been designed to investigate the use of nanoparticulate material for the advancement of cancer research. This Material Transfer Agreement (MTA) permits the exchange of materials and associated information between NCI and the party defined below as "Provider."

Provider: _____

1. Provider agrees to transfer to NCI the following Research Material. Being aware of possibility that constant improvement of the Research Material, both parties understand and agree that future transfer of similar material related to the Research Material will be determined by mutual agreement and documented by electronic mail communications which makes reference to this MTA. Such additional transfers will then be covered by the terms of this MTA:

2. The Research Material and associated information from the Provider will be used only for research purposes by NCI, National Institute of Standards and Technology (NIST), and Food and Drug Administration (FDA) and by NCI's Federally Funded Research and Development Center (FFRDC) contractor and its subcontractors, according to the terms of Article 8 below. This Research Material will not be used for commercial purposes by the aforementioned recipients such as production or sale, for which a commercialization license may be required. NCI agrees to comply with all Federal rules and regulations applicable to the Research Project and the handling of the Research Material. The NCL assumes that the Provider has acquired and secured Provider's Intellectual Property (IP), as appropriate, prior to submitting the Research Material to the NCL for characterization.

   2(a). Are Research Materials of human origin? ☐ Yes ☐ No

   2(b). If yes in 2(a), were Research Materials collected according to 45 CFR Part 46, "Protection of Human Subjects"?
   ☐ Yes (Please provide Assurance Number: _____) ☐ No
   ☐ Not Applicable (Materials not collected from humans)

3. This Research Material will be used solely in connection with the following research project ("Research Project") described as follows and under suitable containment conditions:

   See Addendum 1: "NCL Business Plan: "Interaction Between the NCL and Nanotechnology Providers"

4. In all oral presentations or written publications concerning the Research Project, both parties will acknowledge the other Party's contribution unless requested otherwise. To the extent permitted by law, both Parties agree to treat in confidence, for a period of three (3) years from the date of

its disclosure, any of disclosing Parties written information about this Research Material that is stamped "CONFIDENTIAL," except for information that was previously known or that is or becomes publicly available or that is disclosed to the Parties without a confidentiality obligation or that has been permitted in writing by the disclosing party. Any oral disclosures between the Parties shall be identified as being CONFIDENTIAL by written notice from the disclosing Party to the receiving Party within thirty (30) days after the date of the oral disclosure. Either Party may publish or otherwise publicly disclose the results of the Research Project, but if either Party has given CONFIDENTIAL information to the other Party such public disclosure may be made only after the Receiving Party has had thirty (30) days to review the proposed disclosure to determine whether it includes any CONFIDENTIAL information, except when a shortened time period under court order or the Freedom of Information Act pertains.

5. This Research Material represents a significant investment on the part of Provider. Except as provided under Article 8, NCI'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 her or his direct supervision without advance notification of Provider except as provided under Article 8. When the Research Project is completed, the NCL will archive a sample of the Research Material for future reference. Any remaining Research Material will then be disposed of, if so directed by Provider.

6. This Research Material is provided as a service to the research community. IT IS BEING SUPPLIED TO NCI 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. No indemnification for any loss, claim, damage, or liability is intended or provided by either Party under this Agreement. Each Party shall be liable for any loss, claim, damage, or liability that said Party incurs as a result of said Party's activities under this Agreement, except that NCI, as an agency of the United States, assumes liability only to the extent as provided under the Federal Tort Claims Act (28 USC Chapter 171 Sections 2671-2680).

7. NCI will inform Provider of any inventions made using the Research Material, and after consultation with Provider, NCI, in consultation with NIST and FDA as needed, will decide whether to file a patent application on any such invention. If NCI files a patent application, the Provider will be given the opportunity to negotiate for a license in accordance with 37 CFR Part 404. Provider shall retain title to any patent or other intellectual property rights in inventions made solely by its employees.

8. NCI's Nanotechnology Characterization Laboratory is working in collaboration with the FDA and NIST, and is operated in part by NCI's FFRDC, which is subject to a Determination of Exceptional Circumstances (35 USC §202(a)(ii)), under which patent rights in subject inventions made using the Research Materials are assigned to the U.S. Government. NCI's FFRDC is currently operated by SAIC-Frederick, Inc. Accordingly, Provider authorizes NCI to transfer Research Material and information to FDA, NIST and/or its FFRDC, and its subcontractors.

9. Unless required by law and in accordance with Article 4, ninety (90) days after providing the data and results developed from the Research Project to the Provider, said data and results will be made publicly available by NCI and at NCI's discretion.

10. Provider 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). It is further understood and agreed that Provider may not publicly distribute Research Data provided by the NCI developed under this Research Project without explicit written consent from the NCI.

11. All materials must be transported/shipped to the NCL in accordance with all applicable laws, regulations, and environmental, health, and safety provisions.

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

Signatures on next page

Any false or misleading statements made, presented, or submitted to the Government, including any relevant omissions, under this Agreement and during the course of negotiation of this Agreement are subject to all applicable civil and criminal statutes including Federal statutes 31 USC §§3801-3812 (civil liability) and 18 USC §1001 (criminal liability including fine(s) and/or imprisonment).

For NCI:

_____ _____
Date Authorized Signature for NCI and Title

NCI's Official and Mailing Address for correspondence related to this agreement:

Technology Transfer Branch
National Cancer Institute
Fairview Center, Suite 500
1003 West 7th Street
Frederick, MD 21702

For Provider:

_____ _____
Date Provider's Investigator and Title

_____ _____
Date Authorized Signature for Provider and Title

Provider's Official and Mailing Address:

_____
_____
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Addendum 1 to the NCL MTA
"NCL Business Plan: "Anticipated Interaction Between the NCL and Nanotechnology Providers"

Your nanotechnology particle/material/device/strategy has been selected for characterization by the NCL because it has the potential to impact cancer therapeutics or diagnostics.

The NCL will characterize your technology by subjecting it to a panel of assays to determine its efficacy, safety, and potential for human use in clinical cancer trials. Those assays will analyze the technology's physical characteristics, *in vitro* properties, and *in vivo* behavior in animal models. The assay cascade is anticipated to take at least 12 months. You can expect to be invited to at least two data reviews during NCL's characterization.

Characterization by the NCL is a government-provided service; there are no fees or charges.

Physical samples of your technology will be submitted to the National Institute of Standards and Technology (NIST) and the FDA for characterization, as needed and described in the NCL Business Plan.

Data gleaned from the NCL assay cascade are intended to be included in an investigator-led filing of an Investigational New Drug (IND) with the FDA. These data by themselves will not be sufficient to meet FDA's requirements for an IND. If NCL's assays predict favorable *in vivo* safety and efficacy, NCI and NCL anticipate your organization will want to pursue the translation of your technology into clinical applications.

The NCL assumes that you have acquired and secured your intellectual property (IP) prior to submitting your nanotechnology to the NCL for characterization. Given the "multifunctional" nature of nanotechnology platforms, your technology may be one component in a larger system that is used in clinical research. As an example, scientists at the NCL may chemically "tag" your nanoparticles/material with compounds (e.g., gadolinium) that aid in monitoring/tracking its *in vivo* efficacy.

Information and data related to your nanotechnology strategy will be presented to NCL's Scientific Oversight Committee, to aid in the evaluation of your technology.

The NCL reserves the right to cease characterizing your technology if that option is determined to be in the best interests of NCI.

The NCL is a national resource intended to advance nanotechnology research and development related to cancer therapy and diagnostics. Once characterized, the data generated from your material may be presented in scientific and public forums if such data are deemed to benefit the cancer research community. The NCL will wait at least 90 days after data are provided to you before disclosing them in a public forum. This public disclosure pertains only to data generated at the NCL; your company's proprietary/confidential information will be protected by the NCL in accordance with the Material Transfer Agreement.