

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 NCI 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 NCI 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:

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.