Foundation for the National Institutes of Health
BIOMARKERS CONSORTIUM CONFIDENTIALITY POLICY

For purposes of the Biomarkers Consortium, this Biomarkers Consortium Confidentiality Policy supersedes the FNIH Confidentiality Policy for FNIH Managed Projects and the FNIH Confidentiality Policy Addendum for The Biomarkers Consortium.

It is the policy of the Foundation for the National Institutes of Health (FNIH) that Confidential Information, as that term is defined below, will only be discussed by persons and entities involved in Biomarkers Consortium ("BC") activities under an appropriate confidential disclosure agreement ("CDA") executed by the disclosing party(ies) and the receiving party(ies), which identifies the permitted scope of disclosure, and the permitted use of the Confidential Information[1]. It is the intention of FNIH and the BC Executive Committee that all employees of the relevant parties would be bound by the CDA so that information can be shared on a need to know basis with the appropriate subset of employees.

For purposes of this Confidentiality Policy "Confidential Information" includes, but is not limited to, documents, associated materials and information provided (whether written or oral) in connection with BC activities disclosed by a party (the "Disclosing Party") to a Participant under a confidential disclosure agreement or a non-disclosure agreement and identified in writing as confidential by the Disclosing Party; *provided, however*, Confidential Information shall not include any of the foregoing that (i) can be demonstrated to have been in the public domain or publicly known at the time of disclosure to the Participant; (ii) can be demonstrated to have been in the possession of or that can be demonstrated to have been readily available to the Participant from another source prior to disclosure thereto in connection with his or her association with FNIH; (iii) becomes part of the public domain or publicly known by publication or otherwise, not due to any unauthorized act by the Participant; (iv) can be demonstrated to have been independently developed or acquired by the Participant without reference to or reliance upon such Confidential Information; or (v) is required to be disclosed by law or court of competent jurisdiction, provided, the Participant had promptly notified the Disclosing Party of such order or request and, prior to any such disclosure, had permitted the Disclosing Party to oppose such disclosure by appropriate legal action.

[1] As a regulatory agency and custodian of applicant information, FDA will not in the normal course disclose confidential information. Any such disclosure will be required to comply with the laws and regulations applicable to that agency.