JOHNS HOPKINS PANSCAN II COLLABORATOR AGREEMENT

Governing Access to, and Use and Disclosure of, Pan Scan Data
Maintained in the NIH dbGaP Database

This Collaborative Agreement (the "Agreement") is between The Johns Hopkins University ("JHU"), a not-for profit educational institution in Baltimore Maryland, employer of Dr. Alison Klein, and _____ ("Institution"), employer of Dr. _____ "Collaborator," to govern the access to, and use of, certain human genomic and other data ("Pan Scan Data"). These Pan Scan Data are maintained by the National Institutes of Health ("NIH") in a controlled-access database ("dbGaP"). Dr. Klein, under whose direction the Pan Scan data were created, wishes to permit authorized Collaborators to access and use Pan Scan data for specific research purposes, subject to the terms and conditions in this Agreement.

1. <u>Scope.</u> Collaborators may not request, and NIH may not provide, any Pan Scan data that are not "de-identified" according to the requirements of the HIPAA Privacy Rule. All requests for Pan Scan data are also subject to review and approval by an NIH Data Use Committee ("DUC").

2. <u>Authorized Parties</u>. Institution will limit access to Pan Scan to the Collaborator named below, and other authorized study team members working on the research (collectively the "Authorized Parties"), all of whom must agree to abide by the terms of this Agreement. Institution will allow access only for genome-wide analysis of pancreatic cancer, in projects approved by the NIH DUC. This Agreement does not authorize the Institution or any Authorized User to publish, present, or otherwise publicly disclose the Pan Scan Data.

   <u>Name of Collaborator</u>: _____

   Collaborator's Signature: _____

   The Collaborator will assure that Authorized Parties comply with the terms of this Agreement.

3. <u>Conditions of Access and Use</u>. The Institution will:

   a. Limit use or disclosure of the Pan Scan Data to the individuals and purposes specified in this Agreement, and not permit any use or disclosure of the Pan Scan Data to re-identify or contact Pan Scan Data subjects.

   b. Use appropriate safeguards (including, but not limited to, the principles of responsible research use and data handling of genomic datasets defined in the *NIH GWAS Data Sharing Policy* and the current *dbGaP Security Best Practices*) to prevent use or disclosure of the Data other than as provided for by this Agreement.

c. Report to Dr. Alison Klein [410-955-3511] and to The Johns Hopkins Privacy Officer (5801 Smith Avenue, McAuley Hall, Suite 310, Baltimore, MD 21209; Phone: 410-735-6509; Fax 410-735-6521) within 24 hours any use or disclosure of the Pan Scan Data not provided for by this Agreement of which Institution or Collaborator becomes aware, and to cooperate fully, as permitted by law, with Johns Hopkins University and the Johns Hopkins Health system in any investigation initiated into the circumstances of the unauthorized use or disclosure.

d. Institution will retain control over the Pan Scan Data and will not further distribute or sell Pan Scan Data to any third party (including agents or contractors). Collaborators who leave the Institution during the term of this Agreement must document the destruction of all Pan Scan Data through submission of a final Data Use Report, as described below.

e. Institution will require Collaborator to submit to Dr. Alison Klein (aklein1@jhmi.edu) an annual Data Use Report describing how Pan Scan Data have been used, and detailing any results generated, or publications or presentations resulting from any use of Pan Scan Data. Reports will also summarize plans for future studies involving any Pan Scan Data, any violations of the terms of this Agreement, and any information about intellectual property resulting from use of the Pan Scan Data. Collaborators who are not submitting a renewal agreement (as described in Section 5, below), shall submit a final Data Use Report that certifies the destruction of all Pan Scan Data received from dbGaP.

f. In the event that Institutional policies limit destruction of research data, Institution shall notify Dr. Alison Klein in writing and continue to extend the protections of this Agreement to the Pan Scan Data. Institution's and Collaborator's Authorization to use or disclose Pan Scan Data for any purpose, except as required by law, shall expire upon expiration of this Agreement.

5. <u>Term and Termination</u>. The term of this Agreement shall begin on the date that Pan Scan Data are made accessible to the Collaborator ("Effective Date") and continue for one calendar year, unless otherwise terminated in writing by JHU. The parties acknowledge and agree that JHU may terminate this agreement immediately, and revoke the grant of access to any JHU genomic data, if, in the view of JHU, Institution or Collaborator has breached this Agreement.

6. <u>Relief</u>.   The parties agree that any breach or threatened breach of this Agreement may result in irreparable harm with no adequate remedy at law, and that JHU shall therefore be entitled to seek equitable or injunctive relief to enforce this Agreement without posting a bond. Institution shall indemnify and hold harmless JHU and its affiliated and collaborating institutions for any loss, claim, damage, or liability incurred by the aforementioned as a result of Institution's access to, or use or disclosure of, Pan Scan Data.

7. <u>Construction and Jurisdiction</u>. This Agreement shall be governed by and construed in accordance with the laws of the State of Maryland (excepting any conflict of laws

provisions that would serve to defeat application of Maryland substantive law). The parties agree to the exclusive jurisdiction of the Maryland courts in any dispute arising out of this Agreement.

9. <u>No Assignment</u>. This Agreement may not be assigned by either Party without the prior written consent of the other Party.

JHU   Institution

By:_____   By:_____

Name (Printed): _____   Name (Printed): _____

Title: _____   Title: _____

Address: _____   Address: _____

Date: _____   Date: _____