Material Transfer Agreement  
For Access to Biomaterials and/or Data

This Material Transfer Agreement (hereinafter “MTA” or “Agreement”) is between the National Eye Institute (“NEI” or “Provider”), part of the National Institutes of Health (“NIH”), a component of the Department of Health and Human Services (“DHHS”), and ______________ (“Recipient”), located at __________, for outgoing transfers of human material and for access to data (collectively, “Human Material”), from the eyeGENE® Repository (“Repository”) for research purposes. This MTA will become effective on the date of the last signature hereto (“Effective Date”).

Recipient Investigator (“Investigator”): ________________________________

The Recipient and the Provider agree as follows:

1. **Human Material**

The Provider will transfer to the Recipient the following material:
______________________________, and/or will transfer or provide access to the following data
______________________________ (collectively “Human Material”).

2. **De-identification**

The Recipient will not receive any Identifiable Private Information (IPI) as defined in 45 CFR 46. Instead, only de-identified Human Material, with a code for research purposes that is available only to the NIH Provider, will be supplied. In the event that Recipient receives IPI in error, Recipient agrees to:

(a) Maintain any accidentally transferred IPI in a secure manner that restricts access to any individual not involved in the Research Project [e.g., for paper records – locked file cabinets or continual physical presence in a room that locks or for electronic records – encryption and password protection];
(b) Notify the Provider of any incorrectly transferred IPI;

(c) Destroy or return the IPI at the earliest time at which removal or destruction can be accomplished subject to any instructions from the Provider, and send confirmation of the destruction or return to the Provider.

(d) Make no further use or disclosure of the IPI, except as required by law.

3. **Research Use**

Recipient will only use the Human Material for the Research Project that is described in the attached eyeGENE® Resource Access Application (SF424) for [Insert name or number, as needed, to identify], which is incorporated into and made a part of this MTA. Recipient will not use the Human Material for any commercial purposes, including selling, commercial screening, or transferring Human Material to a third party for commercial purposes. Recipient AGREES THAT THIS HUMAN MATERIAL MAY NOT BE USED IN HUMANS OR FOR ANY DIAGNOSTIC, PROGNOSTIC, OR TREATMENT PURPOSES. The Recipient will comply with all laws, rules and regulations applicable to the handling and use of the Human Material.

The Recipient will allow the use of Human Materials only by Investigator and Investigator’s research team that are under the direct supervision of Investigator and only after they have been informed of and agreed to the provisions and restrictions stated herein. The Investigator will share this document with any research staff that may use the Human Material. Any transfer of Human Material to other than Investigator’s research team requires the advanced written approval of the Provider, except as required by law.

4. **Non-identification**

The Recipient will not contact or make any effort to identify individuals who are or may be the sources of the Human Material, without specific written approval from the Provider. For Human Material made available by the Repository for which participants may be re-contacted for future research, the Investigator may request additional information about the Human Material. The Recipient agrees that if Recipient requires additional information about the Human Material, it will contact the Provider to request the additional information.

5. **Federal Wide Assurance (FWA) and Human Subjects Review**

Recipient is covered by a Federal Wide Assurance (FWA) issued by the United States Department of Health and Human Services (HHS) Office of Human Research Protections, and Investigator will comply with all applicable federal and state laws for the use of this data, which may include 45 C.F.R. Part 46.

6. **Non-transferability and Change of Institution**

The Investigator acknowledges that he/she will only use the Human Material while associated with the Recipient institution. Investigator will not use the Human Material at any other institution. If the Investigator moves to a new institution, the Human Material will not be
transferred from the Recipient institution until an updated MTA naming the new institution obtained.

7. **Research Use Reporting**

Investigator will provide a brief Progress Report summarizing the progress of the Research Project specified in data access request after one year, and annually thereafter until completion of the research or termination of this MTA. The Progress Report is submitted in accordance with OMB#0925-0001 (Research and Research Training Grant Applications and Related Forms) and will include a brief update on the research, including the potential significance of any findings and plans for future research; any resulting scientific presentations with the name, bibliographic citation (if any) and submission date; any publications resulting from the use of data from the eyeGENE® Repository with the title, authors, bibliographic citation, and submission date of the publication; any breaches in data security (for example, accidental data distribution beyond approved users); a brief description of any non-proprietary downstream intellectual property generated or intended to be generated as a result of using this data; and analyzed and raw data collected thus far.

In addition, upon conclusion of the Research Project or termination of this Agreement, Investigator agrees to provide a comprehensive, written, final report (“Final Report”) to Provider with all analyzed and raw data, results, and conclusions of the Research Project.

All analyzed and raw data included in the reports required under this Article 7 will be submitted to eyeGENE BRICS meta-study or through another means agreed upon by Provider and Recipient.

8. **Data Sharing with Third Parties**

Data sharing plans incorporating third party sources (ex. dbGaP) must be provided in advance and in writing to be approved by the Provider to ensure appropriate use in consideration of existing consent and protocol language. Data sharing plans may be submitted anytime during the Research Project.

9. **Confidential Information**

All Confidential Information that is transferred between Provider and Recipient is subject to the following:

All information to be deemed confidential under this MTA shall be clearly marked "CONFIDENTIAL" by the disclosing Party and maintained in confidence by the Recipient for a period of three (3) years from the Recipient’s receipt of the Confidential Information. Any Confidential Information that is orally disclosed must be reduced to writing and marked "CONFIDENTIAL" by the disclosing Party and such notice must be provided to the receiving Party within thirty (30) days of the oral disclosure.

For the purposes of this MTA, Confidential Information includes any scientific or business data relating to the Human Material that a Party asserts are confidential and proprietary, except for data that:
a. have been published or otherwise publicly available at the time of disclosure to the receiving Party; or

b. were in the possession of or were readily available to the receiving Party without being subject to a confidentiality obligation from another source prior to the disclosure; or

c. have become publicly known, by publication or otherwise, not due to any unauthorized act of the receiving Party; or

d. the receiving Party can demonstrate it developed independently, or acquired without reference to, or reliance upon, such Confidential Information; or

e. are required to be disclosed by law, regulation, or court order.

10. **Publication and Acknowledgement of eyeGENE®**

The Investigator will refer to the eyeGENE research ID in corresponding manuscripts and will acknowledge eyeGENE® in all oral and written presentations, disclosures, and publications resulting from any analyses of Human Material. An example of a possible acknowledgment is:

“The DNA samples and data used for the analyses described in this manuscript were obtained from the National Eye Institute – National Ophthalmic Genotyping and Phenotyping Network (eyeGENE® - Protocol 06-EI-0236 which has been funded in part from the National Institutes of Health/National Eye Institute, under Contract No. HHS-N-260-2007-00001-C. We would like to thank the eyeGENE® participants and the eyeGENE® Research Group for their valuable contribution to this research.”

11. **Fitness for Use**

The Human Material is provided as a service to the research community. IT IS BEING SUPPLIED TO THE Recipient WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. The Provider makes no representations that the use of the Human Material will not infringe any patent or proprietary rights of third parties.

12. **Indemnification**

No indemnification for any loss, claim, damage, or liability is intended or provided by either Party under this MTA. 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 MTA, except that the Provider, as an agency of the United States, may be liable only to the extent provided under the Federal Tort Claims Act (28 U.S.C. Chapter 171). No indemnification for third party claims is intended or implied by either Party.

13. **Public Posting of Investigator Information and Privacy Act Notification**
Investigator understands that information about the research use may be posted on a public website that describes the projects of approved users of the Repository. The information may include Investigator’s name, institution or organization, project name, a description of the research objectives, design and analysis plan, and a non-technical summary of the planned research. Investigator agrees to provide the information requested herein and on the attached SF 424. Investigator agrees that information collected from him or her as part of this Agreement and SF 424 may be made public in part or in whole for tracking and reporting purposes. This Privacy Act Notification is provided pursuant to Public Law 93-579, Privacy Act of 1974, 5 U.S.C. Section 552a. Authority for the collection of the information requested below from the recipient comes from the authorities regarding the establishment of the National Institutes of Health, its general authority to conduct and fund research and to provide training assistance, and its general authority to maintain records in connection with these and its other functions (42 U.S.C. 203, 241, 289l-1 and 44 U.S.C. 3101), and Section 301 and 493 of the Public Health Service Act. These records will be maintained in accordance with the Privacy Act System of Record Notice 09-25-0156 (http://oma.od.nih.gov/ms/privacy/pa-files/0156.htm) covering "Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the Public Health Service, HHS/PHS/NIH/OD." The primary uses of this information are to document, track, and monitor and evaluate use of the eyeGENE® Repository, as well as to notify recipients of updates, corrections or other changes to the database. Investigator understands that he or she may have my contact information updated or removed from the system by making this request through the website.

Investigator understands that the Federal Privacy Act protects the confidentiality of his or her NIH records. The NIH and any sites they designate to distribute the eyeGENE® Repository data will use the data collected from recipients for the purposes described above. In addition, the Act allows the release of some information in his or her records without his or her permission; for example, if it is required by members of Congress or other authorized individuals. Investigator understands that the information requested is voluntary, but necessary for him or her to obtain access to data.

14. **Termination**

This Agreement will become effective upon final signature below by an authorized representative and will expire when the Research Project is completed. Recipient will remain bound by the terms of this Agreement until, in accordance with Article 7 of this Agreement, the Final Report has been received by Provider.

Either Party may terminate this MTA without cause with thirty (30) days written notice to the other Party, except, in the case of breach by Recipient, Provider can terminate the Agreement immediately. Upon completion of the Research Project or termination of this Agreement, any remaining Human Materials including all data will be destroyed.

15. **Applicable Law**

This MTA shall be construed in accordance with Federal law as applied by the Federal courts in the District of Columbia.
Signatures

By signing and dating this MTA and SF 424, Recipient and Institutional Signing Official certify our agreement to the NIH principles, policies and procedures for the use of NIH eyeGENE® Repository dataset(s) as described in this document. We further acknowledge that we have shared this document and the NIH policies and procedures with any research staff who will use the eyeGENE® Repository dataset(s) and other appropriate institutional staff and officials.

Any communication or notice to be given shall be forwarded in writing to the respective addresses listed below.

For the Recipient:
Name of Recipient Institution: ________________________________________________
Recipient’s Authorized Representative (See Instructions and Guidelines for Requesters)
Name (typed or printed): ________________________________________________
Title of Institutional Official: ________________________________________________
Signature of Institutional Official: ________________________________________________
Date: ________________________________________________
Investigator (typed or printed): ________________________________________________
Signature: ________________________________________________

For the Provider:

______________________________________________________  Date: _______________
Belinda Seto, Ph.D., Deputy Director, National Eye Institute

______________________________________________________  Date: _______________
David Schneeweis, Ph.D., Technology Development Coordinator, NEI

______________________________________________________  Date: _______________
Chairman of the eyeGENE® Repository Data/Resource Access Committee

To contact the eyeGENE® Network:
Write: National Eye Institute, NIH Building 10, Room 10N226, 
10 Center Drive, MSC 1860 Bethesda, MD 20892-1860
Call: 301-435-3032; OR Fax: 301-480-3787
E-mail: neiyeugeneproinfo@nei.nih.gov