PROWL LASIK Data Sharing Policy

BRICS Informatics System Data Use Agreement for PROWL Data

Approval to access PROWL data from the Biomedical Research Informatics Computing System (BRICS) is for research purposes only. Although Personally Identifiable Information (PII) is not included in this dataset, patient level data is included. Therefore, approved users are expected to protect data privacy, confidentiality, and security. Approved users agree not to share data with others unless those users also sign the Data Use Agreement (DUA). Approved users also agree to not release the data onto other public websites. In the event that requests, or data usage raise concerns or violate the DUA with respect to privacy and confidentiality, risks to populations, groups or study participants, or other relevant concerns, the NEI will consult with other experts as appropriate and take steps appropriate to the violation of the DUA.

Expectations Defined in the Data Sharing Policy for Investigators

The detailed expectations are enumerated in the individual sections of this data sharing policy, and summarized as follows:

Investigators submitting BRICS data are expected to:

- Submit a Data Submission Form, providing assurance that all data are submitted in accord with applicable laws and regulations, and that the identities of research participants will not be disclosed to the BRICS Informatics System; and
- Upload ALL data to BRICS on a regular basis.

Investigators requesting and receiving BRICS data are expected to:

- Submit a Data Access Request;
- Protect data confidentiality;
- Ensure that data security measures are in place;
- Not share with individuals or make accessible via public websites any of the data from datasets obtained from the BRICS Informatics System;
- Notify the Data Access and Quality Committee of policy violations;
- Submit progress reports if requested; and
- Include acknowledgements of the BRICS Informatics System in all publications and presentations.

Oversight and Governance of BRICS

BRICS Data Sharing Policy addresses (1) data sharing procedures, (2) data access principles, and (3) issues regarding the protection of research participants during the submission of, storage of, and access to data within the BRICS Informatics System. The goal

of the policy is to advance science for the benefit of the public through the creation of a centralized Federal data repository for research information. The principles contained in this policy were developed by the BRICS Policy Committee and are consistent with existing NIH polices on data sharing. The NIH recognize that scientific, ethical, and societal issues relevant to this policy are evolving, and have established a Policy Committee to oversee implementation and data use practices. The agencies will revisit and revise the policy and related practices as appropriate.

Data Management

Protecting Research Participants

The potential for public benefit to be achieved through sharing research data is significant. However, the broad data distribution goals of BRICS highlight the importance of protecting the privacy of the research participants and the confidentiality of their data. BRICS Data Sharing Policy includes steps to protect the interests and privacy concerns of individuals, families, and identifiable groups who participate research. The informed consent process is a critical step and subject consent forms in prospective studies include language similar to the following:

> "All links with your identity will be removed from the data before they are shared. Only de- identified data which do not include anything that might directly identify you will be shared with approved BRICS users and the general scientific community for research purposes."

NEI and NIH make every attempt to ensure patient/participant data is used as per the participant's signed informed consent document. For retrospective studies conducted before the development of BRICS, the agencies anticipate considerable variation in the extent to which data sharing and future research have been addressed within the informed consent documents. The submitting institution will determine whether a study is appropriate for submission to BRICS (including an Institutional Review Board (IRB) and/or Privacy Board review of specific study elements, such as participant consent). Some studies may require additional consent of the research participants, which may take considerable time. To ensure the security of the data held in the Informatics System, the NIH Center for Information Technology (CIT) will employ multiple tiers of data security based on the content and level of risk associated with the data.

BRICS will establish and maintain operating policies and procedures to address issues including, but not limited to, the privacy and confidentiality of research participants, the interests of individuals and groups, data access procedures, and data security mechanisms. These will be reviewed periodically by the BRICS oversight bodies as appropriate.

Non-Research Use of Data

As agencies of the Federal Government, the NIH are required to release Government records in response to a request under the Freedom of Information Act (FOIA), unless they are exempt from release under one of the FOIA exemptions. Although the BRICS-held data will be coded, and the NIH will not hold direct identifiers to individuals within the BRICS Informatics System, the agencies recognize the personal and potentially sensitive nature of the data. The NIH believe that release of un-redacted BRICS datasets in response to a FOIA request would constitute an unreasonable invasion of personal privacy under FOIA Exemption 6, 5 U.S.C.§ 552 (b)(6). Therefore, among the safeguards that the agencies foresee using to preserve the privacy of research participants and confidentiality of data are the redaction of individual-level genotype, phenotype, and other clinical data from disclosures made in response to FOIA requests and the denial of requests for un-redacted datasets.

In addition, the NIH acknowledge that legitimate requests for access to data made by law enforcement offices to BRICS may be fulfilled. The NIH will not possess direct identifiers within the BRICS Informatics System, nor will the agencies have access to the link between the data code and the identifiable information that may reside with the primary investigators and institutions for particular studies. The release of identifiable information may be protected from compelled disclosure by the primary investigator's institution if a Certificate of Confidentiality is or was obtained for the original study. The NIH explicitly encourage investigators to consider the potential appropriateness of obtaining a Certificate of Confidentiality (http://grants.nih.gov/grants/policy/coc/) as an added measure of protection against future compelled disclosure of identities for studies planning to collect genome-wide association data. These confidentiality provisions may not apply to military subjects' chains of command.

Data Submission

NIH-supported human research studies—including both intramural and extramural studies—may be required to deposit data into the BRICS Informatics System. Research studies funded by other agencies and groups may also deposit data into the BRICS Informatics System, pending review by the BRICS Policy Committee in collaboration with the external funding source on a case-by-case basis, deferring to pre-existing policies, regulations, and constraints. Investigators applying for funding from participating agencies will be asked to include a data sharing plan consistent with BRICS policy as part of their application and are expected to use the CORE Common Data Elements (CDEs) at a minimum.

BRICS Operations team will work with researchers to map their study variables to specific CDEs. In addition, BRICS will consult with researchers to ensure the formats of the CDEs collected are compatible with the BRICS Informatics System. In addition to CDE variables, BRICS will accept raw data from imaging, biomarker, or physiologic studies, additional supporting documentation as follows:

- the study protocols;
- manual of operations;
- variables measured;
- case report forms; and
- other relevant documents.

All data and information will be submitted to a high security network within the CIT through a secure transmission process, including the supporting documentation:

Data submitted to the BRICS Informatics System will be de-identified such that the identities of data subjects cannot be readily ascertained or otherwise associated with the data by the BRICS staff or secondary data users. In addition, de-identified data will be coded using a unique code known as a Global Unique Identifier (GUID). Use of the GUID minimizes risks to study participants because it keeps one individual's information separate from that of another person without using names, addresses, or other identifying information. The unique code also allows BRICS to link together all submitted information on a single participant, giving researchers access to information that may have been collected elsewhere. The GUID is a computer-generated alphanumeric code [example: 1A462BS] that is unique to each research participant (i.e., each person's information in BRICS—or each subject's record—has a different GUID). BRICS will assist investigators in how to create the GUID, which is an essential requirement for uploading data to BRICS.

Investigators submitting datasets to BRICS are expected to certify that an appropriate IRB has considered such risks and that the data have been de-identified in accordance with NIH regulations before the data are submitted. In addition, in the event that requests raise questions or concerns related to privacy and confidentiality, risks to populations or groups, or other relevant topics, the BRICS Data Access and Quality Committee (DAQC) will consult with other experts as appropriate.

Submissions of data to BRICS shall be accompanied by a certification signed by the Principal Investigator to assure that:

- The data submission is consistent with all applicable laws and regulations, as well as institutional policies;
- The appropriate research uses of the data and the uses that are explicitly excluded by the informed consent documents are delineated;

- The identities of research participants will not be disclosed to the BRICS Informatics System; and
- An IRB of the submitting institution and/or Privacy Board, as applicable, reviewed and verified that:
    - The submission of data to the BRICS Informatics System and subsequent sharing for research purposes are consistent with the informed consent of study participants from whom the data were obtained;
    - The investigator's plan for de-identifying datasets is consistent with the standards outlined above;
    - The risks to individuals, their families, and groups or populations associated with data submitted to the BRICS Informatics System have been considered; and
    - The genotype and/or phenotype data to be submitted were collected in a manner consistent with NIH regulations and policies.

While the agencies expect data sharing through this policy, circumstances beyond the control of investigators may preclude submission of research data to the BRICS Informatics System.

Applications submitted to these agencies for support of research in which the above expectations for data submission cannot be met will be considered for funding on a case-by-case basis by the relevant agency. Investigators are encouraged to submit a short list of planned papers on primary and secondary study objectives to their science officers when negotiating data sharing requirements.

Submitting investigators and their institutions may use the GUID as a means to request removal of data on individual participants from the BRICS Informatics System in the event that a research participant withdraws his/her consent. However, data that have been distributed for approved research use will not be retrieved.

BRICS Data Access

BRICS will provide descriptive summary information of submitted data for general public use. Individuals and institutions seeking data from the BRICS Informatics System will be expected to meet data security measures (such as physical security, information technology security, and user training). Users will agree, among other things, to:

- Use the data only for their personal use;
- Protect data confidentiality;
- Follow appropriate data security protections;
- Follow all applicable laws, regulations and local institutional policies and procedures for handling BRICS data;
- Not attempt to identify individual participants from whom data within a dataset were obtained;
- Not sell any of the data elements from datasets obtained from the BRICS Informatics System;

- Not share with individuals any of the data from datasets obtained from the BRICS Informatics System;
- Agree to report, in real time, violations of the BRICS Data Sharing Policy to the NEI;
- Adhere to the BRICS Data Sharing Policy below with regard to publication; and
- Provide progress reports on research using BRICS data if requested.

Publication

The NEI and the NIH strongly encourage collaboration, but at a minimum all investigators who access BRICS data are expected to acknowledge the funding organization(s) that supported their work, if applicable, the Contributing Investigator(s) who conducted the original study, and the BRICS Informatics System in all resulting presentations, disclosures, or publications of the analyses. Submitters have made a substantial long-term contribution to BRICS by submitting data to the Informatics System. NEI and the NIH seek to encourage appropriate data use and collaborative relationships by outside investigators with the Submitters and to ensure that the contribution of the Submitters is appropriately acknowledged.

If publishing research manuscripts, Data Recipients should submit manuscripts to the NEI for administrative review at least four weeks prior to submission for publication. This review is not a scientific review, but an administrative review to ensure that the terms of the user agreement have been met, the description of BRICS procedures are accurately identified, and BRICS and the original researchers are appropriately acknowledged. These administrative reviews will take no longer than two weeks.

Steps to Request Query Access to the BRICS Informatics System

1. Read the BRICS Informatics System Data Use Certification (DUC) below.

Provide a scanned copy of the signed DUC Recipient Information and Certifications page when requesting an account to BRICS (with Query and Study privileges) at https://prowl.nei.nih.gov.

3. Access Request Review: The NEI will review requests to access the BRICS Informatics System. Such reviews are generally completed within 10 business days.

4. The NEI will notify BRICS staff if the access request has been approved, and an account will then be provided. Users will receive an automated notification of their account update with any modified user name, passwords, or instructions for accessing the BRICS Informatics System.

5. Optional: BRICS System Training (if request approved): Contact BRICS through NEI-DataCommons-ops@mail.nih.gov to discuss specific training needs the user may have and schedule the training.

Data Use Certification (DUC) for the Biomedical Research Informatics Computing System (BRICS)

The Biomedical Research Informatics Computing System, or BRICS, is a comprehensive but customizable bioinformatics system designed for every stage of research. A modular, web-based system, BRICS makes the performance of research studies and clinical trials faster, simpler, and more collaborative. Promoting optimal use on a national scale of this resource will require a large and concerted effort, which may exceed the research capacity of currently investigators. NEI and the NIH have responsibility to the public in general, and to the scientific community, in particular, to encourage the use of these resources to achieve rapid scientific progress. To take full advantage of such resources and maximize their research value, it is important that data be made available, on appropriate terms and conditions, to the largest possible number of qualified investigators in a timely manner. Data collected by the Submitters have been stripped of all individual identifiers, but the unique and intrinsically personal nature of derivative data of which are included in BRICS, combined with the recent technological capacity and cost, has altered the framework through which "identify-ability" can be defined. To protect and assure the confidentiality and privacy of all participants, the Recipient who is granted access to these data is expected to adhere to the specifications of this DUC. Failure to do so could result in denial of further access to data and subject the Recipient to any other applicable penalties and actions.

Definitions

For purposes of this agreement:
"Data" refers to the information that has been collected and recorded from participants in NEI studies, regardless of the source of funding. Data from study participants were collected through the periodic examinations and follow-up contacts conducted pursuant to the Submitters' Cooperative Agreement grants, other grants, contracts, and other NEI studies conducted independent of NEI or NIH.

A "Submitter" is defined as a researcher who has submitted data to the BRICS Informatics System, according to the policies laid out in the BRICS Informatics System Submission Agreement. The Submitter may have had a past or current/active grant, contract, or consulting agreement with NEI or NIH, one of its contractors, or any other funding source.

The "Recipient" is a Principal Investigator or individual who seeks access to data from BRICS. The Recipient requests access to study data at his/her sole risk and at no expense to the study, NEI, and NIH.

"Patients" or "Participants" are those individuals who have participated in a clinical study or trial.

Terms and Conditions

I request approval to access data and/or images from the Biomedical Research Informatics Computing System (BRICS) for research purposes. I agree to the following terms:

1. **Sole Use of Data.** These data will be used by Recipient solely. Recipient agrees that data will only be stored on secure systems for personal use by the Recipient. Data will not be shared on publicly accessible websites. However, the Recipient may reference BRICS access to the data publicly.

2. **Non-transferability of Agreement.** This DUC is not transferable. Each Recipient must complete a Data Use Agreement.

3. **Non-Identification of Subjects.** Recipient agrees that data will not be used, either alone or in conjunction with any other information, in any effort whatsoever to establish the individual identities of any of the subjects from whom data were obtained. Recipient agrees to notify BRICS as soon as possible if, upon use of BRICS data, the Recipient discovers identifying information in those data.

4. **GUID and Access to Submitted Data.** The Global Unique Identifier (GUID) is a computer-generated alphanumeric code that is unique to each research participant. The GUID allows BRICS to link together all submitted information on a single participant, giving researchers access to information even if the data were collected at different locations or

through different studies. If Recipients request access to data on individuals for whom they themselves have previously submitted data to BRICS, they may gain access to more data about an individual participant than they themselves collected. Consequently, these research activities may be considered "human subjects research" and may require that they obtain institutional IRB approval of their Research Project.

5. **Data Disclaimers.** Recipient agrees that NEI and NIH do not and cannot warrant the results that may be obtained by using any data included therein. NEI and NIH disclaim all warranties as to the accuracy of the data in BRICS or the performance or fitness of the data for any particular purpose.

6. BRICS **Notification BRICS of Publication.** Prompt publication or other public disclosure of the results of the Research Project is required. Recipient agrees to notify BRICS via email NEI-DataCommons-ops@mail.nih.gov as to when and where a publication (or other public disclosure) of a report from the Research Project will appear.

7. **No Distribution of Data.** Recipient agrees to retain control over data, and further agrees not to transfer data, with or without charge, to any other entity or any individual, except for collaborators with approved DUCs. Recipient agrees not to sell the data in any form to any entity or individual or to distribute the data to anyone other than his/her research staff and collaborators with an approved DUC, who will also agree to the terms within this DUC.

8. **Acknowledgments.** Recipient agrees to acknowledge the contribution of the BRICS bioinformatics platform, the relevant BRICS dataset identifier(s) (a serial number), and the Submitter(s) in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of data using the BRICS tools, whether or not Recipient is collaborating with Submitter(s). The manuscript should include the following acknowledgement or other similar language:

Data and/or research tools used in the preparation of this manuscript were obtained and analyzed from the controlled access datasets distributed from the NEI- and NIH-supported Biomedical Research Informatics Computing System (BRICS) Informatics Systems. BRICS is a collaborative biomedical informatics system created by the Department of Defense and the National Institutes of Health to provide a national resource to support and accelerate research in NINR.

Dataset identifier(s): [provide]. This manuscript reflects the views of the authors and may not reflect the opinions or views of the NEI, NIH, or of the Submitters submitting original data to BRICS Informatics System.

If the Research Project involves collaboration with Submitters or BRICS staff then Recipient will acknowledge Submitters as co-authors, if appropriate, on any publication. In addition, Recipients agree to include a reference to BRICS Informatics System datasets analyzed and to cite BRICS and the federal funding sources in abstracts as space allows.

9. **Non-Endorsement; Liability.** Recipient agrees not to claim, infer, or imply endorsement by the United States Government, the Department of Defense, the Department of Health & Human Services, or the National Institutes of Health of the Research Project, the entity, or personnel conducting the Research Project or any resulting commercial product(s). The United States Government assumes no liability except to the extent provided under the Federal Tort Claims Act (28 U.S.C. § 2671-2680).

10. **Recipient's Compliance with Institutional Requirements.** Recipient acknowledges that access, if provided, is for research that is approved by the Institution, which must be operating under an Office of Human Research Protections (OHRP)-approved Assurance. Furthermore, Recipient agrees to comply with all applicable NEI and NIH rules for the protection of human subjects, and other federal and state laws for the use of these data. Recipient agrees to report promptly to BRICS any problems involving risks to subjects or others. This DUC is made in addition to, and does not supersede, any of Recipient's institutional policies or any local, State, and/or Federal laws and regulations that provide additional protections for human subjects.

11. **Privacy Act Notification.** In order to access the BRICS Informatics system, the Recipient agrees to provide the information requested below.

The Recipient agrees that information collected from the Recipient, as part of the Data Access Request, 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 NIH, 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 the use of the BRICS Informatics datasets, as well as to notify interested recipients of updates, corrections or other changes to the database.

The Federal Privacy Act protects the confidentiality of the Recipient's NEI and NIH records. NINR and the NIH and any sites that are provided access to the datasets will have access to the data collected from the Recipient for the purposes described above. In addition, the Act allows the release of some information in the Recipient's records without his/her permission; for example, if it is required by members of Congress or other authorized individuals. The information requested is voluntary, but necessary for obtaining access to data.

12. **Security.** Recipient acknowledges the expectations set forth by the attached "BRICS Information Security Best Practices" for the use and security of data.

13. **Progress Update.** Recipient will provide to NEI a summary of research accomplishments upon request.

14. **Amendments.** Amendments to this DUC must be made in writing and signed by authorized representatives of all parties.

15. **Termination.** Either party may terminate this DUC without cause when provided 30 days written notice to the other party. Recipients agree to immediately report violations of BRICS Policy to the NEI Additionally, NEI and NIH may terminate this agreement with 5 days written notice if the NEI and NIH determine, in their sole discretion, that the Recipient has committed a material breach of this DUC. NEI and NIH may, in their sole discretion, provide Recipient with 30 days notice to remedy a breach before termination. Upon termination of the DUC, use of the data must be discontinued. Closed accounts may be reactivated upon submission of an updated Informatics System Access Request and DUC.

16. **One Year Term and Access Period.** Accounts are valid for one year and will be renewed annually by the BRICS operations team. Accounts that remain inactive for 12 consecutive months may be closed at the discretion of NEI and NIH.

17. **Accurate Representations.** Recipient expressly certifies that the contents of any statements made or reflected in this document are truthful and accurate**.**

BRICS Information Security Best Practices

The purpose of these Security Best Practices, which are subject to applicable law, is to provide minimum security standards and best practices for individuals who use BRICS to submit, access, and analyze data. Keeping BRICS information secure through these best practices is important. Subject to applicable law, Recipients agree to immediately report breaches of data confidentiality to the BRICS DAQC.

Best Practices

• Do not attempt to override technical or management controls to access data for which you have not been expressly authorized.
• Do not use your trusted position and access rights to exploit system controls.
• Ensure that anyone directed to use the system has access to, and is aware of, BRICS Information Security Best Practices and all existing policies and procedures relevant to the use of BRICS.
• Follow the BRICS password policy which includes:
• Choose passwords of at least seven characters including at least three of the following types of characters: capital letters, lower case letters, numeric characters and other special characters.
• Change your passwords every six months.
• Protect your BRICS password from access by other individuals.
• Notify BRICS staff, as permitted by law, at NEI-DataCommons-ops@mail.nih.gov of security incidents, or any incidents of suspected fraud, waste or misuse of BRICS or when access to BRICS is no longer required.

Security Standards

• Protect the data, access is solely authorized to the Recipient.
• When you download BRICS data, download the data to a secured computer or server with strong password protection.
• For the computers hosting BRICS data, ensure that they have the latest security patches and are running virus protection software.
• Make sure the data are not exposed to the Internet or posted to a website that may be discovered by Internet search engines such as Google or MSN.
• If you leave your office, close out of data files or lock your computer. Consider the installation of a timed screen saver with password protection.
• Avoid storing data on a laptop or other portable medium. If storing data on such a device, encrypt the data. Most operating systems have the ability to natively run an encrypted file system or encrypt portions of the file system. (Windows = EFS or Pointsec and Mac OSX = File Vault)
• When finished using the data, destroy the data or otherwise dispose of it properly, as permitted by law.

Recipient Information and Certifications

Date:

First Name:

Last Name:

Degree:

Street Address:

City:

State/Province: _

Zip/Postal Code:

Country:

Telephone:

E-mail Address:

By signing and dating this DUC as part of requesting access to data in BRICS, I certify that I will abide by the DUC, and the NEI and NIH principles, policies and procedures for the use of the BRICS Informatics System. I further acknowledge that I have shared this document and the NEI and NIH policies and procedures with any research staff who will participate in the use of BRICS.

Signature:

Date:

Inquiries and Requests to Submit Data to BRICS should be sent to: Office of BRICS Operations
National Institutes of Health, Center for Information Technology (CIT) 12 South Dr. RM 2041
Bethesda, MD 20892
Email: NEI-DataCommons-ops@mail.nih.gov