

Biomedical Research Informatics Computing System (BRICS)

Data Sharing Policy for NINR Funded P20 and P30 Pilot Studies

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Overview

The Biomedical Research Informatics Computing System, or BRICS, is a comprehensive but customizable bioinformatics system designed for every stage of your research. A modular, web-based system, BRICS makes the performance of research studies and clinical trials faster, simpler, and more collaborative. It was developed to promote collaboration, accelerate research, and advance knowledge on the characterization, prevention, diagnosis and treatment of various diseases. BRICS/NINR Informatics System provides a common platform and standardized format for data collection, retrieval and archiving, while allowing for flexibility in data entry and analysis. Additional information and detailed implementation guidance related to the BRICS/NINR Informatics System can be found at <http://BRICS/NINR.nih.gov>.

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/NINR data are expected to:

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

Investigators requesting and receiving BRICS/NINR data are expected to:

- Submit a Data Access Request;
- Protect data confidentiality;
- Ensure that institution based standard data security measures are in place; Data security measures must also conform to the NINR Data and Safety Monitoring Policy.
- Notify the BRICS NINR Operations team and NINR program staff of policy violations;
- Include acknowledgements of the BRICS/NINR Informatics System in all publications and presentations.

Applicability

This Data Sharing Policy applies to approved NINR and NIH P20 and P30 extramural research pilot projects.

Oversight and Governance of BRICS/NINR

BRICS/NINR 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/NINR 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 NINR research information. The principles contained in this policy were developed by the BRICS Operations and NINR program staff and are consistent with existing NIH and NINR policies on data sharing. The NINR and 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

Consent of the research participants should be done in accordance to the Institutional Review Boards. To ensure the security of the data held in the Informatics System, the BRICS/NINR platform will employ multiple tiers of data security based on the content and level of risk associated with the data. BRICS/NINR has 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/NINR/NIH oversight bodies as appropriate.

Non-Research Use of Data

As agencies of the Federal Government, the NINR and 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/NINR-held data will be coded, and neither the NINR nor the NIH will hold direct identifiers to individuals within the BRICS/NINR Informatics System, the agencies recognize the personal and potentially sensitive nature of the genotype-phenotype data. The NINR and the NIH believe that release of un-redacted BRICS/NINR 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 genetic 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 NINR and the NIH acknowledge that legitimate requests for access to data made by law enforcement offices to BRICS/NINR may be fulfilled. Neither the NINR nor the NIH will possess direct identifiers within the BRICS/NINR 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.

Data Submission

Approved NINR P20/P30 Centers pilot projects will be required to deposit data into the BRICS/NINR Informatics System.

NINR program staff will work with researchers to map their study variables to specific CDEs. BRICS/NINR will consult with researchers to ensure the formats of the CDEs collected are compatible with the BRICS/NINR Informatics System. In addition, BRICS/NINR will accept raw data for Biomarker CDEs approved by NINR program staff.

Additional supporting documentation to provide details on the data will be accepted, but not required, 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 BRICS/NINR Informatics system through a secure transmission process, including the supporting documentation:

Data submitted to the BRICS/NINR 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/NINR 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/NINR 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/NINR—or each subject's record—has a different GUID). BRICS/NINR will assist investigators in how to create the GUID, which is an essential requirement for uploading data to BRICS/NINR.

Investigators submitting datasets to BRICS/NINR are expected to certify that an appropriate IRB has considered such risks and that the data have been de-identified in accordance with NINR and 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 NINR program staff and BRICS operations will consult with other experts as appropriate.

Submissions of data to BRICS/NINR 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/NINR 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/NINR 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/NINR Informatics System have been considered; and
 - The biomarker and clinical data to be submitted were collected in a manner consistent with NINR and NIH regulations and policies.

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

Submitting investigators and their institutions may use the GUID as a means to request removal of data on individual participants from the BRICS/NINR Informatics System in the event that a research participant withdraws his/her consent. Users that have accessed data for withdrawn GUIDs will be notified that all data use should cease and if the data has been further distributed, the recipient should be notified not to use the data. Investigators will be notified to destroy all data for withdrawn GUIDs. However, data that have been distributed for approved research use will not be retrieved.

Data Submission Schedule

Data include all research and clinical assessments and information as approved by the NINR program.

See the list of additional documents under the “Data Submission” section above. All data from pilot projects must be submitted during the grant award period. If any error in data is found during the data submission period of the project, the project lead will contact the BRICS Operations team to assist in correcting the data submission

BRICS/NINR Data Sharing Schedule

One (1) year after the end of the pilot study, the data submitted to the BRICS/NINR Informatics System that are used in the study will be made available to all qualified and approved researchers (Recipients).

Investigators are also strongly encouraged to collaborate and share data throughout the study to accelerate research and advance knowledge. To facilitate collaboration, [data access request forms](#) that are submitted before the end of the pilot study to BRICS operations for initial review are then forwarded on to the relevant Submitters. The Submitters may choose to collaborate and/or to provide access to all or some of their **Experimental Data**, in which case the data will be made available to the data Recipients.

BRICS/NINR Data Access

BRICS/NINR will provide descriptive summary information of submitted data for general public use. Access to data for research purposes will be provided by the BRICS NINR Operations team. The BRICS operations will operate according to common principles and follow similar procedures to ensure the consistency and transparency of the BRICS/NINR data access process. The BRICS NINR Operations team will review the applications of investigators requesting data and make a determination based on their affiliation with a research institution, and on the basis of the reason for the request. It is anticipated that most requests will be appropriate and can be approved rapidly, and that only a few will require clarification. In the event that requests raise concerns related to privacy and confidentiality, risks to populations or groups, or other concerns, the NINR program staff and BRICS operations will consult with other experts as appropriate. A request to appeal the decision is allowed and will be reviewed by the BRICS/NINR Policy Committee.

Investigators and institutions seeking data from the BRICS/NINR Informatics System will be expected to meet data security measures (such as physical security, information technology security, and user training) and will be asked to submit a [Data Access Request](#) that is signed by the investigator. Data Access Requests should include a brief description of the proposed research use of the requested BRICS/NINR data. Investigators will agree, among other things, to:

- Use the data only for the approved research; if the Recipient wants to use the data to investigate additional research questions, a second data access request form must be submitted.
- Protect data confidentiality;
- Follow appropriate data security protections;
- Follow all applicable laws, regulations and local institutional policies and procedures for handling BRICS/NINR 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/NINR Informatics System;
- Not share with individuals other than those listed in the request any of the data elements from datasets obtained from the BRICS/NINR Informatics System;
- Agree to the list of approved research uses within the BRICS/NINR Informatics System along with his/her name and organizational affiliation;
- Provide IRB numbers and expiration dates;
- Agree to report, in real time, violations of the BRICS/NINR Data Sharing Policy to the NINR Program staff and BRICS NINR Operations team.
- Adhere to the BRICS/NINR Data Sharing Policy below with regard to publication; and
- Provide annual progress reports on research using BRICS/NINR data.

Data Quality

The NINR and the NIH are implementing a two-tiered data control procedure for information submitted to the BRICS/NINR Informatics System to ensure that the information submitted has undergone reviews for accuracy, completeness, and availability. The first level of quality control is performed by the researcher who is expected to certify the accuracy of the information prior to

submission. The second level of quality control occurs when data is submitted to the BRICS/NINR Informatics System for broad research access. BRICS/NINR will provide a period of three months to allow the Submitter and the agencies to undertake activities to review the completeness of the submission. Such efforts include verifying that the information received by BRICS/NINR is complete (i.e., not missing records intended for submission), contains no identifying information, displays correctly, and that the BRICS/NINR Toolset functions as expected with the information. Should the university or institution determine that additional time is necessary to ensure the quality of the submitted information (e.g., time necessary to remedy concerns), the agencies may opt to extend the quality control period as necessary in the interest of science. After quality control measures are satisfied, the submitted information will be certified as accurate by the submitting researcher.

Publication

The NINR and the NIH strongly encourage collaboration, but at a minimum all investigators who access BRICS/NINR data are expected to acknowledge the funding organization(s) that supported their work, the Contributing Investigator(s) who conducted the original study, and the BRICS/NINR Informatics System in all resulting presentations, disclosures, or publications of the analyses.

Acknowledgments. In any and all oral and written presentations, disclosures and publications based upon dataset(s) submitted to BRICS, Submitter agrees to cite BRICS, the relevant BRICS dataset identifier (a serial number), and the Submitters' federal research funding sources in each publication to which such datasets contribute (for abstracts, as space allows). The publication should include the following acknowledgement:

Data used in the preparation of this article reside in the National Institute for Nursing Research (NINR) and National Institutes of Health (NIH)-supported Biomedical Research Informatics Computing System (BRICS) in [dataset identifier]. This manuscript reflects the views of the authors and does not reflect the opinions or views of the NINR or the NIH.

In any and all oral and written presentations, disclosures, and publications resulting from substantive analyses of data using BRICS tools, Submitter agrees to acknowledge the contribution of the BRICS bioinformatics platform. The manuscript should include the following acknowledgement or similar other 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 NINR cdRNS collaborative biomedical informatics system.
Dataset identifier (DOI): [provide]. This manuscript reflects the views of the authors and does not reflect the opinions or views of the NINR or NIH.

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

Inquiries

Specific questions about this policy should be directed to:

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