# PicnicHealth Data Access Policy

**PURPOSE**

The purpose of the Data Access Policy is to outline the steps required for external researchers to request, access and use research data sets maintained by PicnicHealth for use in research as described in this Policy.

**POLICY STATEMENT**

The data sets will be released to Principal Investigators (PI) who meet certain criteria and are approved by PicnicHealth only for permitted research purposes. PicnicHealth holds the right to deny a data set request. PIs will comply with this Policy and the terms of the Data Access Agreement when using and disclosing a data set.

**SCOPE**

This Policy applies to all research data generated, owned and managed by PicnicHealth (each a “data set”). This Policy applies to PicnicHealth employees, contractors, PIs, research organizations and others that do business with PicnicHealth.

**DEFINITIONS**

*Principal Investigator (“PI”):* The lead person responsible for research oversight, including primary responsibility for access, use, analysis, and other use of research data set obtained in compliance with this Policy and through a data access agreement.

*Research:* a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

*Research data set*: de-identified data set consist of records of research that are necessary for the reconstruction and evaluation of research results and the events and processes leading to those results, regardless of the form of the media on which they are recorded. Research data sets are de-identified using the statistical method under the HIPAA Privacy Rule.

*Research Organization:* A nonprofit or academic organization at which the principal investigator conducts research.

*Review Committee:* A PicnicHealth Review Committee will evaluate the proposed use of a research data set based on the criteria set out in this Policy. The Review Committee is also responsible for ongoing review of this use of research data sets and compliance with this Policy.

**POLICY**

**1. Permitted Usage**

PicnicHealth makes research data sets available to Principal Investigators at Research Organizations free of charge for non-commercial research purposes only. Principal Investigators, Research Organizations and their research teams may not use data or combine data for future research purposes without express written consent of PicnicHealth. Research Organization and PI agree that research data sets will not be used in any studies unless said studies are disclosed and approved as part of the Research Project.

**2. Requests for Data**

Principal Investigators may submit an accurate and complete *Data Access Request Form* for access and use of a research data set for eligible research.The Review Committee shall review the completed *Data Access Request Form* and evaluate to ensure it is consistent with the eligibility criteria set out in this Policy.

**3. Eligibility Criteria**

Research data sets will only be used for eligible research which meet the following criteria:

* Appropriately credentialed and experienced PI and researchers
* No commercial usage permitted
* Important and relevant scientific questions
* Appropriate scientific study design to answer question(s) posed
* Data is available and study powered to answer question(s) posed
* IRB approved research

**4. Review of Proposed Research**

All proposals will be reviewed and approved or denied by PicnicHealth. All requests must be accompanied by approval of document(s) including informed consent document and approvals from the institutional review board. If the PI’s review board awards the research project an “exempt status,” documentation must still be provided detailing the approval of exemption. PI are expected to submit timely annual review and reports related to research including institutional review board approvals for such continuing research.

**ACCESS**

The Recipient will be provided access to a secure data sharing platform. PicnicHealth will limit access to only the PI and necessary members within the research team. After completion of the Research or the expiration or termination of the Data Use Agreement, access to the platform will be terminated.

**Responsibilities For Use**

* ***Research and Data Oversight.*** The Research Organization and PI are responsible for ensuring that their research team complies with this Policy. All research data must have a named custodian. The PI is the custodian of research data, and therefore the individual ultimately responsible for following best practices in their field of research and for ensuring that the research data set is managed according to this policy.
* ***Data Management.*** The PI is responsible for the collection, management, and retention of research data but may delegate related data management tasks to members of the research team. The PI is responsible for ensuring that designees have the training necessary to maintain the integrity of the data and adhere to this policy.
* ***Publication.*** All publications and presentations resulting from these data will state that the original research using the dataset was conducted by PicnicHealth and any other partners, and be consistent with the Data Use Agreement.
* ***Use of Research Data Set.*** Datasets shall be made available as established by PicnicHealth. Data will be used (analyzed and disseminated) only in the manner stipulated in the proposal and accepted by PicnicHealth.
* ***Compliance with Participants' Informed Consent*.** Recipient and Recipient’s PI agree that Data and derivatives thereof will not be used for any purpose contrary to a participant’s applicable signed informed consent document(s) and authorizations. Recipient and Recipient's PI agree to consult with PicnicHealth and ascertain, specifically and in detail, the terms and conditions of applicable PicnicHealth informed consent documents.
* ***No Re-Identification.*** Recipient and Recipient’s PI agree that Materials and/or Data will not be used, either alone or in conjunction with any other information, in any effort to determine the individual identities of any of the participants from whom Data and/or Materials were obtained or derived.

**Storage and Security**

Research data should be managed, shared, and stored according to best practices during analysis and final storage, including following PicnicHealth access controls, data retention and other security policies. This includes:

* + - Adopting an orderly secure system of data organization and communicating the chosen system to all members of a research group and applicable administrative personnel.
    - Utilizing current best practices for appropriate storage options (i.e. encryption, device management, controlled servers).
    - Implementing access controls and performing risk assessments of information security systems where research data sets reside.
    - Achieving consistency with IRB approved protocol which includes security, confidentiality and privacy requirements which meet or exceed PicnicHealth standards.

**Destruction and Return of Research Data Sets**

Upon expiration or termination of the Data Use Agreement, or upon request by PicnicHealth, Recipient shall destroy all Data as directed by PicnicHealth.