

LONI

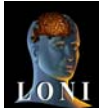
Policies & Procedures

Arthur W. Toga, Director

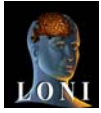
December 2, 2002

Version 1

Laboratory of Neuro Imaging



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1 Introduction

Welcome to the Laboratory of Neuro Imaging. The Laboratory of Neuro Imaging (LONI) seeks to improve understanding of the brain in health and disease through the development of computational algorithms and scientific approaches for the comprehensive and quantitative mapping of brain structure and function.

The laboratory is dedicated to providing resources for the acquisition, analysis and storage of brain image data to the neuroscience community. We encourage collaborations between institutions and scientists, disseminate the products of our research and share the resources of our laboratory.

The policies and procedures set forth in this document govern appropriate use of the LONI resources. These policies and procedures constitute a living document and are subject to change by the laboratory. These policies apply to all users and machines on the LONI network, in addition to the University's policies. The University's policies can be accessed via <http://www.bol.ucla.edu/policies/>

2 Computing Resources

The Laboratory of Neuro Imaging provides the neuroscience community with access to a broad array of supercomputing, visualization, storage and networking resources. Our goal is to provide a secure and highly-reliable environment in which investigators can conduct their research. To this end LONI:

- provides a fault-tolerant, high-availability storage area network designed to ensure near 24/7 functionality and accommodate current and projected storage requirements
- employs a high-performance computing environment with separate graphics and computation systems to optimize function-specific procedures and provide fault tolerance by eliminating any single point of failure
- provides use of the LONI Image Database which has been constructed for effective archival and protection of image data
- makes available software packages for image analysis, visualization and modeling
- provides access to a well validated set of protocols developed for the processing of imaging data

2.1 General Understanding

LONI's supercomputing, storage and networking systems are shared resources. Any action that inhibits or has the potential to inhibit the ability of authorized users to utilize these resources must be considered a policy violation. The laboratory will use the University's mandate on acceptable computing resource usage to determine whether a violation has occurred. In addition, for situations not explicitly enumerated in written policy, LONI will exercise a case-by-case evaluation. Laboratory members and collaborators are expected to exercise good judgment in their use of the computing resources. Users are encouraged to consult LONI systems administration (Administration) when questions arise regarding potentially inappropriate computer usage.

2.2 Availability

The LONI supercomputing resources are generally available 24 hours per day, 7 days per week. Users will be notified, in advance by system broadcast and/or e-mail, of scheduled down times.



2.3 Security

2.3.1 User Accounts

User accounts may be obtained for approved, registered collaborations. Instructions on becoming a LONI collaborator are covered in Section 3.

2.3.2 Passwords

Users agree to help assume all reasonable measures to keep their accounts secure. Failure to do so may result in the cancellation of the account. The list below describes some ways in which accounts may be kept secure. The list is not exhaustive and, for any doubts and additional questions, users should contact Administration.

- Do not communicate your password to anyone. If group access to the same data is necessary Administration can set up the appropriate permissions.
- Choose a password that you can easily remember but that is not immediately associated to you. Birth dates, names of spouses, partners, and pets are usually bad choices. Choose something obscure but easy for you to remember.
- Never write down your password where others might see it. Keep it in memory. Do not post your password on your terminal or program it in one of your terminal's function keys. Never include your password in an e-mail message. No one from LONI is authorized to ask you to communicate your password.
- Do not leave your terminal unattended while you are logged in to your account.
- Report any moved, added, deleted, or altered files.

2.4 Restrictions

2.4.1 Secured Shell Requirements

The laboratory relies on Secured Shell (SSH) for encrypted transmission of account information, including passwords, over the network. Any computer that requires a network connection to the LONI systems must use SSH. Furthermore, protocols based on SSH, SFTP and SCP specifically, are to be used in place of FTP and CP for secured data transmission throughout the LONI network. The administration staff will be happy to assist with any SSH-related issues.

2.4.2 Resource Drains

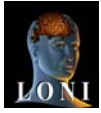
The use of specific UNIX commands known to produce resource drains on the system is prohibited. Examples of such commands are find commands over CXFS and NFS mounted file systems. As an alternative, account holders can use the `-fstype nfs -prune -o` options to avoid excessive burden on the system. Any other user-developed commands that monopolize computing resources and significantly impact the ability of other users are prohibited.

2.4.3 System Usage

If a machine is to be left unattended and unused for more than 1 hour, the user is required to log off. 'Locking' unused machines for extended periods of time prevents others from using the computing resource and is prohibited.

2.5 Machine Requirements

Systems utilizing the LONI network must disable the TELNET, R services and FTP protocols as they are deemed unsecured. In addition, systems should meet the up-to-date CERT security recommendations and implement the latest patches provided by the appropriate OS vendor.



2.5.1 Services

Information, specifically the name, type, MAC address, and services running, on machines with static IP addresses must be entered into LONI's machine database. Services, such as SMTP, web services, etc. cannot be enabled without explicit authorization from LONI administration. This ensures that systems running such services are tracked and administered properly.

2.5.2 Wireless

In order for a machine to utilize LONI's wireless network, a user needs to provide administration with the MAC address, make and model of the machine.

2.5.3 Accounts

Root/administrator accounts or "sudo" equivalent on machines with a static network address must be given to LONI administration for emergency purposes.

2.6 Consequence of Misuse and/or Repeated System Compromise

In the event that a particular machine is compromised, the boot drive must be zeroed using appropriate utilities and a clean install of the operating system must be performed. If a situation is deemed in violation of usage policy, Administration will make three attempts at resolving the issue with the appropriate parties. Failure to do so will result in the loss of computing privileges and/or the removal of the offending machine from the network.

On the first occurrence of a system compromise on a non-LONI administered machine, LONI administration and the other parties involved will meet, discuss and address any security issues and concerns. A second occurrence, if it is due to gross negligence, will result in LONI billing the appropriate parties for service interruption, if any, and time and resources expended by LONI staff on securing the system. Gross negligence entails failure to properly patch a machine after an exploit/vulnerability has been publicized for 14 days. A third occurrence will result in a permanent loss of computing privileges.

3 Collaboration

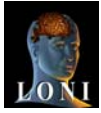
Our collaborations include research projects focused on a variety of neuroscientific problems spanning the range from development to aging, as well as disease processes that influence the structure and/or function of brain. We provide service to collaborators in the form of robust software, access to our computer hardware resources and production of animations and image renderings. Collaborators agree to comply and support the policies and procedures as documented in this manual.

3.1.1 Application

Collaborators are required to provide information regarding their Institution, project and funding status. This requirement is mandated by the funding source. An on-line application form is available at http://www.loni.ucla.edu/NCRR/NCRR_CollabApp.html for this purpose.

3.1.2 Selection

Selection is based upon the promise of a significant scientific relationship. Each of the collaborative projects fit well with the general themes computational anatomy and multi-dimensional modeling. Further, our efforts on their behalf and their contribution to our research is mutually beneficial. These projects provide unusual data sets, either repeated measures or unique populations of individuals of high quality imaging or specific biological problems that present a unique and challenging opportunity for our group. Once selected, a LONI user account will be established for the investigator (or the investigators representative) and e-mail notification provided.



4 Human Subject Data

4.1 Confidentiality

Confidentiality of patient data is a crucial element of any medical research project that involves human subjects. Federal Regulations govern human subjects research and protection of human subject identifying information. The bibliography below contains a list of links to web sites covering various U.S. Government Agencies' policies on patient confidentiality and shared data.

1. DHHS Regulation, standards for privacy of individually identifiable health information
 - a. <http://dhhs.gov/ocr/hipaa/>
 - b. <http://ohrp.osophs.dhhs.gov/>
2. NIH policy on sharing data in research activities
 - a. http://grants1.nih.gov/grants/policy/data_sharing/
 - b. http://grants1.nih.gov/grants/policy/data_sharing/data_sharing_faqs.htm
3. Guidance on the research use of stored samples or data
 - a. http://ohsr.od.nih.gov/info/ninfo_14.php3

This section summarizes relevant patient privacy information and outlines our approach to satisfying the applicable regulations without hindering the research. It reflects a balance between guarding patient confidentiality and achieving research results. To assist collaborators in meeting these regulations, LONI provides tools for ensuring protection of patient identifying information, including data anonymization and de-identification tools.

4.1.1 Overview: Health Insurance Portability and Accountability Act of 1996 (HIPAA)

HIPAA Standards for Privacy of Individually Identifiable Health Information Regulations (45 CFR Parts 46 and 160 through 164) establish requirements for protecting the privacy of individually identifiable health information. These standards apply in all cases where data is acquired by a covered entity.

4.1.2 Definitions

Protected Data (Private Data)

Protected data is private data that could be used by itself or in conjunction with other data to identify a subject. This data cannot be shared.

Limited Data Set

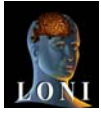
A limited data set contains some information that needs to be de-identified under the Safe harbor Guidelines. However, this data can only be shared through the use of a data use agreement. This data is limited to research purposes only and can be released under the limited data guidelines below.

De-Identified Data

De-identified data is data that has been processed according the HIPAA Safe Harbor Guidelines (see de-identification of data below). This data contains no identifying information and can be released as Public data.

Covered Entity

The Administrative Simplification standards adopted by HHS under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) apply to any entity that is a health care provider that conducts certain transactions in electronic form, a health care clearinghouse or a health plan.



4.1.2.1 *De-identification of data*

Protected health information can be de-identified so that such information may be used and disclosed freely. Under the safe harbor provision 18 enumerated identifiers need to be removed:

1. Names
2. Geographic subdivisions smaller than a state, except for initial three digits of zip code unless this abbreviation contains less than 20,000 people
3. Dates directly related to an individual (visit dates, birth dates)
4. Phone numbers
5. Fax numbers
6. Email addresses
7. Social Security numbers
8. Medical record numbers
9. Health Plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet protocol (IP) address numbers
16. Biometric identifiers including finger and voice prints
17. Full face photographic images and any comparable images
18. Other unique identifiers

Note: age less than 90 (including months, days and hours), gender, ethnicity and other demographic information is allowable. Also, a code can be assigned to the data so that the de-identified data can be re-identified, if the code is not derived from or related to information about the subject.

4.1.2.2 *Facial Anonymization*

Face images may be part of or constructible from certain MR scans. Faces are a direct identifier as described by HIPAA and therefore all scans which allow for this reconstruction should be considered protected health information.

4.1.2.3 *Re-identification*

A subject identifier which allows information de-identified under HIPAA guidelines to re be-identified may be assigned provided that :

- the code is not derived from nor related to information about the individual and is not otherwise capable of being translated so as to identify the individual
- the code is not used or disclosed for any other purpose

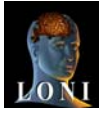
4.1.2.4 *Limited Data Set Definition*

Under the latest HIPAA guidelines (August 14, 2002), a limited data set for research purposes has been added that requires a use agreement be obtained between the recipient of the data and the source.

Under this provision the following may be shared:

- Patient Age (including months, days and hours - any age)
- Patient Visit/Study Dates
- Birth and Death Dates
- Geographic subdivisions - including 5 digit zip code
- Note that the limited data set does not include the catch-all "other unique identifiers" contained in the Safe Harbor Provision.

As before allowable attributes include: Patient Weight, Admitting Diagnosis Description, Ethnic Group, Occupation.



4.2 Human Subject Privacy Strategy

This section outlines a suggested strategy for protecting the confidentiality of human subject data.

Collaborator data are to be used solely for analysis and research. LONI requires all users to give assurance that all data uses will conform to widely accepted standards of practice and legal restrictions that are intended to protect the confidentiality of research subjects. The LONI policies regarding confidentiality of patient data comply with all Federal regulations and guidelines. Sharing of LONI acquired data is in accordance with the HIPAA guidelines for de-identified and/or limited data sets as stated in (45 CFR Parts 160 and 164), Federal Register: August 14, 2002 (Volume 65, Number 160), Pages 53182-53273.

Each investigator is encouraged to examine data collections to ensure that the contents of the collection do not violate explicit or implicit pledges of confidentiality given to respondents or research subjects. Data items that could be used to identify individual respondents should be removed, masked, or collapsed (in conformance to HIPAA safe harbor procedures) unless the investigator has a limited data set agreement in place which provides for the sharing of protected patient information. Investigators choosing to share limited data are encouraged to do so under a data use agreement.

4.2.1.1 Limited Datasets

Access to limited datasets should be limited to researchers who require the additional variables contained in the limited use file and who agree to the terms and conditions contained in a Limited Data Use Agreement. A Limited Data Use Agreement is a legal document between the researcher, her/his employer, and the Principal Investigator. Changes in the employment status of the researcher require the completion of a new Limited Data Use Agreement. An example of a Limited Data Use Agreement is included in the Appendix.

For sharing of a limited data set with a data use agreement, no approval is needed from the individual or IRB. The data use agreement should specify not only the purposes of the limited data set but also the particular data elements or categories of data requested

4.2.1.2 Data Protection Plan

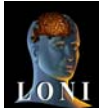
The Data Protection Plan becomes part of the signed agreement between a PI and the Limited Data Investigator(s). If the agreement is executed, all members of the research team with access to the data are contractually obligated to follow all aspects of the Data Protection Plan. The fundamental goal of the protections outlined in this plan is to prevent persons who are not signatories to the Limited Data Use Agreement or the Supplemental Agreement With Research Staff from gaining access to the data. The agreement will not be executed if the plan is not written with sufficient specificity, or if data protections are not deemed adequate.

The Data Protection Plan applies to both the raw data received from a PI as well as any copies made by the research team, and any new data derived solely or in part from the limited data. The plan also should address how output derived from the data will be kept secure. This applies to all computer output, not only direct data listings of the file.

4.2.1.3 Components of the data protection plan

Your Data Protection Plan should contain the following components:

1. Reference to Title of Research Project and Principal Investigators.
2. All locations where copies of the data will be kept.
3. Computing environment in which the data will be used:
 - Computing platform (PC, workstation, mainframe platform)
 - Number of computers on which data will be stored or analyzed



Whether personal computers used in the research project will be attached to a network or will operate independently (stand-alone)

Physical environment in which computer is kept (e.g., in room with public access, in room locked when not in use by research staff)

4. Device(s) on which data will be stored: (on network server, on mainframe computer storage device, on PC hard drive, on removable storage device such as CD, floppy drive, or Zip(R) drive.)
5. Methods of data storage when data are not being used.
6. Methods of transmitting the data between research team members (if applicable).
7. Methods of storage of computer output (in electronic form as well as on paper).

4.3 LONI Image Database

The LONI Image Database has been constructed to provide an effective means for archival and protection of collaborator collected image data. The goal is to provide a convenient mechanism for searching the existence of particular image data while protecting its usage at the same time. We have built the appropriate mechanisms to ensure that no image data or identifying patient information is accessible to the outside world or to any others without the appropriate authorization and the expressed permission to release data from the collaborator that acquired and provided the data.

4.3.1 Database Assistance

The LONI data coordination staff are available to assist investigators in data archival through the LONI Image database. The database may be perused on the LONI web site at:

http://www.loni.ucla.edu/NCRR/NCRR_Data.html.

5 Software

Our focus on computational anatomy and multidimensional modeling has resulted in the development of software packages that deal with aspects of image analysis and modeling. Software descriptions, requirements and downloads are available at our web site:

http://www.loni.ucla.edu/NCRR/NCRR_Software.html

http://www.loni.ucla.edu/ICBM/ICBM_Software.html

6 Support

A variety of support options exist which include a help desk, technical support, consulting services and training. These are described in detail below.

6.1 Technical Support and Monitoring

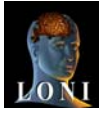
LONI maintains a full time staff devoted to supporting the computing resources including network and performance tuning. This team understands the importance of the research being conducted and the necessity of making LONI resources stable, providing high availability and delivering fast access to computing and data resources.

6.2 Help Desk

In general, help may be obtained by sending e-mail to help@loni.ucla.edu. The help desk is staffed during regular working hours.

6.3 Education and Training

Our goal in training is to provide the most comprehensive arsenal of materials to train investigators both on the theory and philosophy of image analysis, computational anatomy and multidimensional modeling,



as well as the specific applications of software developed at LONI. Training activities are divided into the following areas:

- 1) courses and workshops
- 2) formal training program
- 3) visiting professorship series
- 4) instructional web
- 5) research training program

Additional information and descriptions of each of these activities may be found at the LONI web site:

http://www.loni.ucla.edu/NCRR/NCRR_Courses.html.

6.4 Consulting Services

Faculty and staff within LONI possess expertise in brain development, disorders and function, anatomy, modeling, image analysis and visualization. These experts are available for consultation by appointment. Information about individual lab member's research, interests and contact information may be found at http://www.loni.ucla.edu/About_Loni/people/index.jsp.

7 Web Site

A LONI web site, supports the LONI activities and research projects. The site reports the progress made by the scientific research teams, provides documentation on aspects of LONI resources, and maintains a database of publications generated by investigators. Additional information is available at our home page <http://www.loni.ucla.edu>.

7.1.1 Limitation of Liability

LONI is not liable for any direct, indirect, special, incidental or consequential damages arising out of the use--or the inability to use-- the material on this site. This includes but is not limited to the loss of data or loss of profit, even if LONI was advised of the possibilities of such damages.

7.1.2 Links

While this site may contain links to third-party sites, LONI is not responsible for the content of any linked sites. LONI provides these links as a convenience and does not endorse the companies or contents of any linked sites.

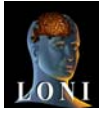
7.1.3 Export of Information

The United States Export Controls laws prohibit the export of certain technical data and software to certain territories. No content from this site may be downloaded or otherwise exported in violation of United States law.

7.1.4 LONI Privacy Policy

When inquiries are e-mailed to us, we store the question and the e-mail address information so that we may respond electronically. Unless otherwise required by statute, we do not identify publicly who sends questions or comment. We will not obtain information that will allow us to personally identify you when you visit our site, unless you chose to provide such information to us. We do not forward your mail outside of LONI nor do we collect your name and e-mail address for any purpose other than to respond to your query. We will only maintain the information as long as needed to respond to your question or to fulfill the stated purpose of the communication.

E-mail sent to LONI may be seen by a number of people who are responsible for answering questions. If the information specialist who answers the mail does not know the answer to your question, your query may be forwarded to another LONI employee more experienced in that area. You should be aware that e-



mail is not necessarily secure against interception. Therefore, if your communication contains sensitive or personal information, you may want to send it by postal mail.

8 Definitions

LONI Resource

Hardware, software and support resources available through LONI's National Center for Research Resource (NCRR).

LONI Collaborators

All investigators (P.I., co-Investigator, or staff) who have a role in the collaborative research project.



9 Appendix

9.1 Application for Limited Data Files

INSTRUCTIONS

Please provide all the information specified below. Additional information may be attached to this form. Please note that only one application per research project is required. However, separate Data Protection Plans and Data Use Agreements are required for each organization represented by the research team.

1. Study Title:
2. Study Number:

Applicant information: (Note: Unless otherwise instructed, the first Principal Investigator listed will serve as the primary contact person.)

Name of Principal Investigator:

Title:

Department (if applicable):

Organization:

Street Address:

City, State, ZIP:

Phone:

Fax:

Email:

Name of Co-Principal Investigator (if applicable):

Title:

Department (if applicable):

Organization:

Street Address:

City, State, Zip:

Phone:

Fax:

Email:

Please provide information on additional Co-Principal Investigators, if applicable.

3. The title of the research project for which the limited file is requested.
4. A short description of research project including research questions, primary methodology, categories of variables to be used (attach additional sheets if required).
5. The types of data from other sources that will be merged with this limited file?
6. The reasons why the public-use data file is not adequate for the research project.
7. How the results of the research will be used, including plans for public dissemination.
8. Names, titles, and affiliations of other members of the research team who will have access to the limited data or to output derived from these data. If not all members have been selected, please list as "unassigned" and indicate the job titles. Include individuals who are employed by different organizations.
9. Number and expiration date of a current NIH Multiple Project Assurances (MPA) Certification.
10. If a member of the proposed research team, including subcontractors, is employed at an organization that does not have an NIH Multiple Project Assurances (MPA) Certification Number:
 - a) Please describe your employer in detail. Include the type of organization, profit/non-profit status, and primary sources of revenue.
 - b) The source(s) of funding for the specific research for which you are applying to use this limited data file? (List name of funding organization, whether funds provided as a grant, contract, or other mechanism.)
 - c) Proprietary interests of the funding organizations listed in the response to above, even if not directly related to the research project described above.



- d) Policies regarding scientific integrity and misconduct, or human subjects research that cover the secondary analysis of LONI data (if applicable).

9.1.1 Limited Data Use Agreement

INSTRUCTIONS

Please submit an original-signature copy of this agreement; this will be countersigned and a copy returned to you.

The Limited Data Investigator and the Receiving Organization agree to the following terms and conditions:

Terms

1. "Limited Data" refers to the original limited data provided by the PI and any fields or variables derived from these data, on whatever media they shall exist. (Aggregated statistical summaries of data and analyses, such as tables and regression statistics, are not considered "derived" for the purposes of this agreement.)
2. "Limited Data Investigator" refers to the investigator who serves as the primary point of contact for all communications involving this agreement. The Limited Data Investigator assumes all responsibility for compliance with all terms of this agreement by employees of the receiving organization.
3. "Principal Investigator(s)" refers to the Limited Data Investigator and any Co-Principal Investigators.
4. "Receiving Organization" refers to the organization employing the Limited Data Investigator.
5. "Research Staff" refers to any individuals other than the "Limited Data Investigator(s)" with access to the limited data.
6. The "Representative of the Receiving Organization" refers to an individual who has the authority to represent your organization in agreements of this sort, such as a Vice President, Dean, Provost, Center Director, or similar official. (Note that a Department Chair is not acceptable unless specific written delegation of authority exists.)

Items Incorporated by Reference

7. The Application for Limited Data is incorporated by reference into this Agreement.
8. The Supplemental Agreement with Research Staff is incorporated by reference into this Agreement.
9. The Data Protection Plan, developed by the Limited Data Investigator, is incorporated by reference into this Agreement.

Ownership of Data

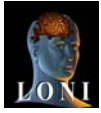
10. Ownership of limited data will be retained by the Principal Investigator. Permission to use limited data by the Investigator(s) and Receiving Organization may be revoked at any time, at their discretion. The Investigator(s) and Receiving Organization must return or destroy all originals and copies of the limited data, on whatever media it may exist, within 5 days of written request to do so.

Access to the Limited Data

11. Access to the limited data will be limited solely to the individuals signing this agreement and the Supplemental Agreement With Research Staff, as detailed in the approved Data Protection Plan. The data may not be "loaned" or otherwise conveyed to anyone other than the signatories to this agreement.
12. Copies of the limited data or any subsequent variables or data files derived from the limited data will not be provided to any other individual or organization without the prior written consent of the PI.

Uses of the Limited Data

13. The limited data will be used solely for the purpose of scientific research, and not for any administrative, proprietary, or law enforcement purposes.



14. The limited data will be used to generate only information that does not allow any individual, family, household, business, or organization to be identified.
15. The limited data will be used solely for the research project described in the Application for Limited Data incorporated by reference into this document.
16. No attempt will be made to identify any individual person, family, household, business, or organization. If an individual person, family, household, business, or organization is inadvertently identified, or if a technique for doing so is discovered, the identification or discovery will be immediately reported to LONI, and the identification or discovery will not be revealed to any other person who is not a signatory to this agreement.
17. No attempt will be made to link this limited data with any other dataset, including other datasets provided by LONI, unless specifically identified in the approved Application for Limited Data.
18. Use of the limited data will be consistent with the receiving organization's policies regarding scientific integrity and human subjects research.

Data Confidentiality Procedures

19. If the Receiving Organization requires a review of research proposals using secondary LONI data by an Internal Review Board/Human Subjects Review Committee or equivalent body, that review has taken place and all approvals have been granted prior to application for use of the limited data.
20. The Receiving Organization will treat allegations of violations of this agreement as allegations of violations of its policies and procedures on scientific integrity and misconduct. If the allegations are confirmed, the Receiving Organization will treat the violations as it would violations of the explicit terms of its policies on scientific integrity and misconduct.
21. The Limited Data Investigator certifies that all aspects of the Data Protection Plan, as approved by the PI, will be followed until which time all copies of the limited data are destroyed.

Destruction of Data Upon Completion of Research Project

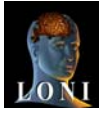
22. The Limited Data Investigator will certify to the PI that all originals and copies of the limited data, on whatever media, will be destroyed at the completion of the research project described in the Application for Limited Use Data or within 5 days of written request from the PI.

Post-Approval Modifications to Submitted Materials

23. If changes in research plans or computer environment will alter the information originally submitted as part of this Agreement, the Limited Data Investigator shall provide the PI with a copy of the revised materials and a memorandum describing the changes in advance of the revisions. These revisions will be considered amendments to this agreement and may not be implemented until written approval is received by the PI.
24. A change in the employer of the Limited Data Investigator requires the execution of a new Limited Data Use Agreement and preparation of a new Data Protection Plan. These materials must be approved by the PI before limited data may be accessed at the new place of employment.
25. When other research staff join the project, they shall submit the Supplemental Agreement with Research Staff. Such supplemental agreements shall be submitted in a timely manner but, in any event, prior to granting other research staff access to the data on whatever media in which the data may exist.

Violation of This Agreement

26. If LONI determines that the Agreement may have been violated, LONI will inform the Limited Data Investigator(s) of the allegations in writing and will provide them with an opportunity to respond in writing within 10 days. LONI may also, at that time, require immediate return or destruction of all copies of the limited data in possession of the investigators. Failure to do so will be determined to be a material breach of this agreement and, among other legal remedies, may be subject to injunctive relief by a court of competent jurisdiction. If LONI deems the allegations unfounded or incorrect, the data may be returned to the Limited Data Investigator under the terms of the original



agreement. If LONI deems the allegations in any part to be correct, LONI will determine and apply the appropriate sanction(s).

27. If LONI determines that any aspect of this agreement has been violated, LONI may invoke these sanctions as it deems appropriate:

- Denial of all future access to limited data files
- Report of the violation to the researcher's Site's office responsible for scientific integrity and misconduct, with a request that the Site's sanctions for misconduct be imposed
- Report of the violation to appropriate federal and private agencies or foundations that fund scientific and public policy research, with a recommendation that all current research funds be terminated, that future funding be denied to the investigator(s) and to all other persons involved in the violation, and that access to other limited data be denied in the future
- Such other remedies that may be available to LONI under law or equity, including injunctive relief

I certify that all materials submitted with this application for this limited data are truthful.

Furthermore, I acknowledge that I am legally bound by covenants and terms of this agreement, and that violation will constitute unethical professional practice and may subject me to the sanctions listed above.

Limited Data Investigator:

Study Title:

Signature:

Date:

Typed Name:

Title:

Site:

Building/Room Number:

Street Address:

City/State/ZIP:

Telephone:

Fax:

Email:

Representative of the Receiving Organization

By signing this agreement, this organization agrees that access to these confidential data will be restricted to authorized persons whose names appear on this agreement and the Supplemental Agreement with Research Staff, and that this organization is legally bound by the covenants and terms of this agreement.

Signature:

Date:

Typed Name:

Title:

Site:

Building/Room Number:

Street Address:

City/State/ZIP:

Telephone:

Fax:

Email:



Representative of the PI

Signature:
Date:
Typed Name:
Title:

PI
Address Here

9.1.2 Supplemental Agreement With Research Staff

INSTRUCTIONS

Please submit an original-signature copy of this agreement. (It will be countersigned and a copy returned to you.) Use additional copies of this page if necessary.

The undersigned staff, in consideration of their use of this limited data certify, the following:

1. That they have read the associated Limited Data Use Agreement, and the Data Protection Plan incorporated by reference into this Agreement.
2. That they are "Research Staff" within the meaning of the Agreement (any research staff other than the Limited Data Investigator).
3. That they will fully comply with the terms of the Agreement, including the Data Protection Plan incorporated by reference into it.
4. That they will not attempt to access this limited data until approved to do so by the LONI Resource PI.

Study Title:
Signature:

Date:
Typed Name
Title/Formal Affiliation with Research Project
Signature

Date
Typed Name
Title/Formal Affiliation with Research Project

The above Research Staff are hereby granted approval to access this limited data:

LONI Resource PI

Date