RTRN DATA SHARING POLICY

Effective Date: July 01,2017

Expiration Date: June 30, 2022

RTRN DATA SHARING POLICY

TABLE OF CONTENT

ABOUT RTRN

The Research Centers in Minority Institutions (RCMI) Translational Research (RTRN) Network unites academic researchers, medical professionals and community partners through technology and health science innovation to reduce health disparities. RTRN was established in 2007 by a memorandum of understanding (MOU) between the minority research universities, colleges and medical schools of the RCMI program under a common goal of fostering collaborations across RCMI institutions, with the aim of improving minority health and reducing health disparities. Collaborations within and beyond the RCMI community are expected to promote joint grant applications and publications and accelerate the pace of basic, clinical and translational research.

Vision: To lead health science innovation that focuses on improving the health of underserved communities and be a valued resource of health-related research for these communities.

Mission: To foster and support inter-institutional collaboration to maximally leverage outcomes, resources and expertise across member RCMI institutions, enhancing research capacity and accelerating the understanding and treatment of diseases, with a focus on those that disproportionately affect underserved communities.

Strategic Goals: To enhance (1) infrastructure to facilitate multi-site, cross-disciplinary translational research, especially research focused on addressing health disparities; (2) processes to increase the efficiency of conducting multi-site clinical trials and translational research and (3) web-based research, training and educational resources for investigators, healthcare providers, research participants and the general public.

NETWORK GOVERNANCE

RTRN's principal investigator provides direction and leadership for the Network's three Centers: the Administrative Coordinating Center (ACC), the Research Coordinating Center (RCC) and the Data Coordinating Center (DCC), which offer expertise, services as well as technical support for the Network's collaborative initiatives and multi-site research study development and implementation.

RTRN Steering Committee is the main governing body of the cooperative network. The role of the Steering Committee is to facilitate all RTRN activities as it relates to conducting research studies, promoting network collaborations, and overseeing RTRN processes and procedures to ensure compliance with all regulatory requirements.

In addition to these members, there is participation from the National Institutes of Health through the RTRN Cooperative Agreement.

PARTICIPATING INSTITUTIONS

RTRN leverages the research infrastructure, resources and expertise of the 18 NIH RCMI-funded institutions that comprise the Network. The major focus is to form multi-institutional research collaborations that focus on addressing health disparities.

RCMI G-12 PROGRAMS

ALABAMA

Center for Biomedical Research
Tuskegee University
Tuskegee, AL
Principal Investigator: Clayton Yates, Ph.D.
334:727-8949
cyates@mytu.tuskegee.edu

DISTRICT OF COLUMBIA

Howard University Center for Computational Biology and BioInformatics (CCBB)
Howard University College of Medicine
Washington, DC
Principal Investigator: William M. Southerland, Ph.D.
202:806-9711
wsoutherland@howard.edu

FLORIDA

FAMU RCMI Pharmaceutical Research Center
Florida Agricultural and Mechanical University
College of Pharmacy and Pharmaceutical Sciences
Tallahassee, FL
Principal Investigator: Karam F.A. Soliman, Ph.D.
850:561-3301
karam.soliman@famu.edu

GEORGIA

Center for Cancer Research and Therapeutic Development
Clark Atlanta University
Atlanta, Georgia
Principal Investigator: Shafiq A. Khan, Ph.D.
404:880-6795
skhan@cau.edu

Morehouse School of Medicine G12 Multidisciplinary Biomedical Research Center
Morehouse School of Medicine
Atlanta, GA
Principal Investigator: Vincent C. Bond, Ph.D.
404:752-1862
vbond@msm.edu

HAWAII

Bioscience Research Infrastructure development for Grant Enhancement and Success
University of Hawaii at Manoa
Honolulu, HI
Principal Investigator: Marla J. Berry, Ph.D.
mberry@hawaii.edu

Program Director: Michelle Tallquist, Ph.D.
808:692-1579
michelle.tallquist@hawaii.edu

LOUISIANA

Xavier's RCMI Cancer Research Program
Xavier University of Louisiana
New Orleans, LA
Principal Investigators: Gene D'Amour, Ph.D.
504-329-6454
gdamour@xula.edu

Guandi Wang, Ph.D.
504:520-5076
gwang@xula.edu

MISSISSIPPI

RCMI-Center for Environmental Health
Jackson State University
Jackson, MS
Principal Investigator: Paul B. Tchounwou, Sc.D., M.S.P.H.
601:979-0777
paul.b.tchounwou@jsums.edu

NEW YORK

Center for Translational and Basic Research
Hunter College
New York, NY
Principal Investigator: Jesus Alexander Angulo, Ph.D.
212:772-5232
jangulo@hunter.cuny.edu

Cellular/Molecular Basis of Development: Research Center

CCBR|CCNY City College of New York
New York, NY
Principal Investigator: Mark Pezzano, Ph.D.
212:650-8559
mpezzano@sci.ccny.cuny.edu

PUERTO RICO

RCMI Program at the Ponce School of Medicine
Ponce School of Medicine
Ponce, PR
Principal Investigator: José A. Torres, Ph.D.
787:840-2575, ext. 2213
jtorres@psm.edu

Universidad Central Del Caribe Biomedical Research Centers
Universidad Central Del Caribe
Bayamón, PR
Principal Investigator: Eddy Ríos, Ph.D., M.P.H.
787:798-4054
Eddy.Rios@ucaribe.edu

Center for Collaborative Research in Health Disparities
University of Puerto Rico Medical Sciences Campus
San Juan, PR
Principal Investigator: Emma Fernández-Repollet, Ph.D.
787:763-9401
e.fernandez@upr.edu

TENNESSEE

Meharry RCMI Program in Womens Health Research
Meharry Medical College
Nashville, TN
Principal Investigator: James E. K. Hildreth, Ph.D., M.D.
Program Director: Maria de Fatima Lima, Ph.D.
615:327-6533
mflima@mmc.edu

TEXAS

RCMI Center for Biomedical and Health Research Excellence
Texas Southern University
Houston, TX
Principal Investigator (Contact PI) Bobby Wilson, Ph.D.
wilson_bl@tsu.edu

Principal Investigator Oyekan Adebayo, Ph.D.
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oyekan_ao@tsu.edu

Program Director Dong Liang, Ph.D.
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RCMI Center for Interdisciplinary Health Research CIHR
University of Texas, San Antonio
San Antonio, TX
Principal Investigators: George Perry, Ph.D.
210:458-4450
George.Perry@utsa.edu

Border Biomedical Research Center
University of Texas, El Paso
El Paso, TX
Principal Investigator: Dr. Robert A. Kirken
Program Director: Dr. Renato Aguilera
915:747-5536
rkirken@utep.edu

RCMI RCTR – U54 PROGRAMS

CALIFORNIA

Accelerating Excellence in Translational Science (AXIS)
Charles R. Drew University of Medicine and Science
Los Angeles, CA
Principal Investigator: Jay Vadgama, Ph.D.
323:563-4853
jayvadgama@cdrewu.edu

GEORGIA

RCMI Translational Research Network (RTRN)
Morehouse School of Medicine
Atlanta, GA
Principal Investigator: Elizabeth Ofili, M.D.
404:752-1970
eofili@msm.edu

RCMI Infrastructure for Clinical and Translational Research (RCTR) (U54)
Morehouse School of Medicine
Atlanta, Georgia
Principal Investigator: Valerie Montgomery-Rice, M.D.
Program Director: Elizabeth Ofili, MD, MPH, FACC

HAWAII

RCMI Multidisciplinary and Translational Research Infrastructure EXpansion Hawaii
University of Hawaii at Manoa
Honolulu, HI
Principal Investigators: Jerris Robert Hedges, M.D., M.S., MMM
808:692-0881
jerris@hawaii.edu

Dr. Noreen Mokuau
808:956-6300

Program Director: Bruce Shiramizu, MD
bshirami@hawaii.edu

PUERTO RICO

Puerto Rico Clinical and Translational Research Consortium
University of Puerto Rico Medical Sciences Campus
San Juan, PR
Principal Investigators: Marcia R. Cruz-Correa, M.D., Ph.D. and Carlos Luciano, M.D.

TENNESSEE

Meharry Clinical and Translational Research center (MeTRC)
Meharry Medical College
Nashville, Tennessee
Principal Investigator: Samuel E. Adunyah, Ph.D.
615:327-6446
sadunyah@mmc.edu

RTRN DATA SHARING POLICY

Introduction

RTRN's principal objective in developing a Network-wide data access and sharing policy is based on the premise that data are a public good and sharing data is both ethical and beneficial. Our goal is to promote the wide use of our data by the scientific community and eventually make more meaningful contributions towards promoting societal wellbeing. However, we remain mindful of the challenges and complexities of data sharing and will continue to make efforts to create a well-functioning research and innovation infrastructure, supported by institutions that are committed to protecting the interests of key stakeholders that are integral to a sustainable data sharing environment.

RTRN is a translational research network comprising 18 RCMI programs which conduct research related to diseases that disproportionately affect African American, Hispanic, Asian and Pacific Islander, and Native American communities. RCMI scientists, in collaboration with community health representatives and industry partners, have pinpointed critical diseases for which they are identifying innovative research approaches. Thus, research teams at the RCMI institutions actively conduct research in high-impact disparity areas such as Cancer, HIV/AIDS and other infectious diseases, Cardiovascular Disease, Neurological Disorders and Mental Health, Environmental Health and Toxicology, and drug therapies. This represents a special source of longitudinal data and scientific evidence on the health and living conditions of underserved populations and an opportunity to better understand the origins and determinants of health disparities.

The data collected by these institutions are unique in several respects and serve multiple functions:

- Provide the opportunity to generate longitudinal data on the prevailing health of African American, Hispanic, Asian and Pacific Islander, and Native American communities across the Nation;

- Serve as platforms for conducting policy-relevant research and for monitoring and tracking health disparities so as to alert relevant stakeholders and identify appropriate interventions;

- Assist in developing standard data-collection methods and in testing and evaluating cost-effective health interventions that will reduce health disparities.

RTRN's data access and sharing policy document seeks to ensure that the Network conforms to national best practices of data sharing. This policy reflects the Network's and its individual members' commitment to responsibly, efficiently and widely share public health research data within and beyond the Network in a sustainable manner. It is also

expected to strengthen the Network's capacity to effectively manage, curate, analyze and publish research outputs and to foster balanced collaborations and partnerships with the scientific community. The scope of this Network policy is restricted to the sharing of those data (falling under different data types mentioned in this policy document) that are submitted by member institutions to the Network.

Definitions

The Network
The RCMI Translational Research Network (RTRN) is made up of 18 RCMI institutions supported by the National Institute on Minority Health and Health Disparities (NIMHD) at the National Institutes of Health (NIH) through G12 and U54 mechanisms.

Principal Investigator
The Principal Investigator of the RTRN Network.

RCMI Member Institution
An institution that operates at least one RCMI program and fulfills all the requirements for full membership of the Network.

Network Activity
An RTRN-initiated and/or sanctioned research activity involving two or more RCMI Member Institutions with a designated Principal Investigator (PI) (not to be confused with the PI of the RTRN Network).

Third-Party Sponsored Activities
Third-party sponsored activities are research activities initiated externally to the Network involving more than one Network member institution and facilitated by and/or conducted in partnership with RTRN.

Contributed Data
Data made available by an RCMI Member Institution to the Network in terms of fulfilling its network membership requirements or in terms of a specific data-use agreement between member institutions and the Network.

Data Categories
This policy refers to the following categories of data.

A. **Institution-Specific Data,** when such data are attributed, are all data generated by and specific to a RCMI member institution.

B. **Network Core Data** are data contributed by an RCMI member institution as a condition of Network membership. These data can be shared in any one of the following forms:

a. Micro-data at a level of a surveillance unit (individual, household, etc.) as defined by OECD Glossary of Statistical Terms. http://stats.oecd.org/glossary/detail.asp?ID=1656

b. Aggregated (indicator) data, which are:
    i. Derived from the core minimum micro-data, or
    ii. Provided in aggregated form directly by an RCMI Member Institution

C. **Network Project Data** are data resulting from Network activities of the following kinds:

a. Network activities that are exclusively based on secondary analysis of data from participating RCMI member institutions.

b. Network activities that involve primary data collection.

Data Sharing
The process of and agreements for making data freely and universally available on the Internet.

Data Owner
The legal entity possessing the right resulting from the act of creating a data record. The record may be a product derived from another, possibly non-data product, which may affect the right.

Data Access
User's ability to access or retrieve data stored within a database or other repository supported by the RTRN DCC.

Data-Sharing Agreement
An official accord between the parties that distinctly establishes which type of data is being shared, the obligations involved, the permissions required and how the data can be used. It ensures the protection of the rights of the data-provider (RCMI institution) and the receiver (RTRN network), by establishing regulations and agreed terms and conditions of use in diffusion to third parties.

Final Research Data
Recorded factual material commonly accepted in the scientific community as necessary to validate research findings. Final research data do not include laboratory notebooks, partial datasets, preliminary analyses, drafts of scientific papers, plans for future research, peer review reports, communications with colleagues, or physical objects, such as gels or laboratory specimens.

Data Access and Sharing Policy

The data access and sharing policy sets out the specific procedures (See diagram below) and prescribes access levels related to various categories of data covered under the policy.

A. Network-Specific Data

When such data are contributed to Network activities they will be subject to the terms of this policy. However, sovereignty over use of the data for institution-specific analyses remains with Member Institutions, including data held at the institution not contributed to the Network or data contributed to the Network but with restrictions regarding certain analyses that are reserved for the institution that submitted the data.

B. Network Core Data

a. Core data sets will be submitted by all member institutions to the DCC technical team, who will conduct quality review and disclosure risk assessment on the data in consultation with RTRN PI, coordinating center directors, and the PIs of RCMI member institutions. Following approval by the Steering Committee the data will be immediately released for network use and within 12 months will be made available for public use through licensed access on the RTRN-DCC Data Repository.

b. Aggregated data will be prepared annually by the designated technical team and released after review by a designated subcommittee of the RTRN Steering Committee (Ethics and Regulatory) and subsequent approval by RTRN PI, coordinating center directors, and Steering Committee members. These data will be shared through open access on the RTRN-DCC Data Repository as soon as the approval process is completed.

C. Network Project Data

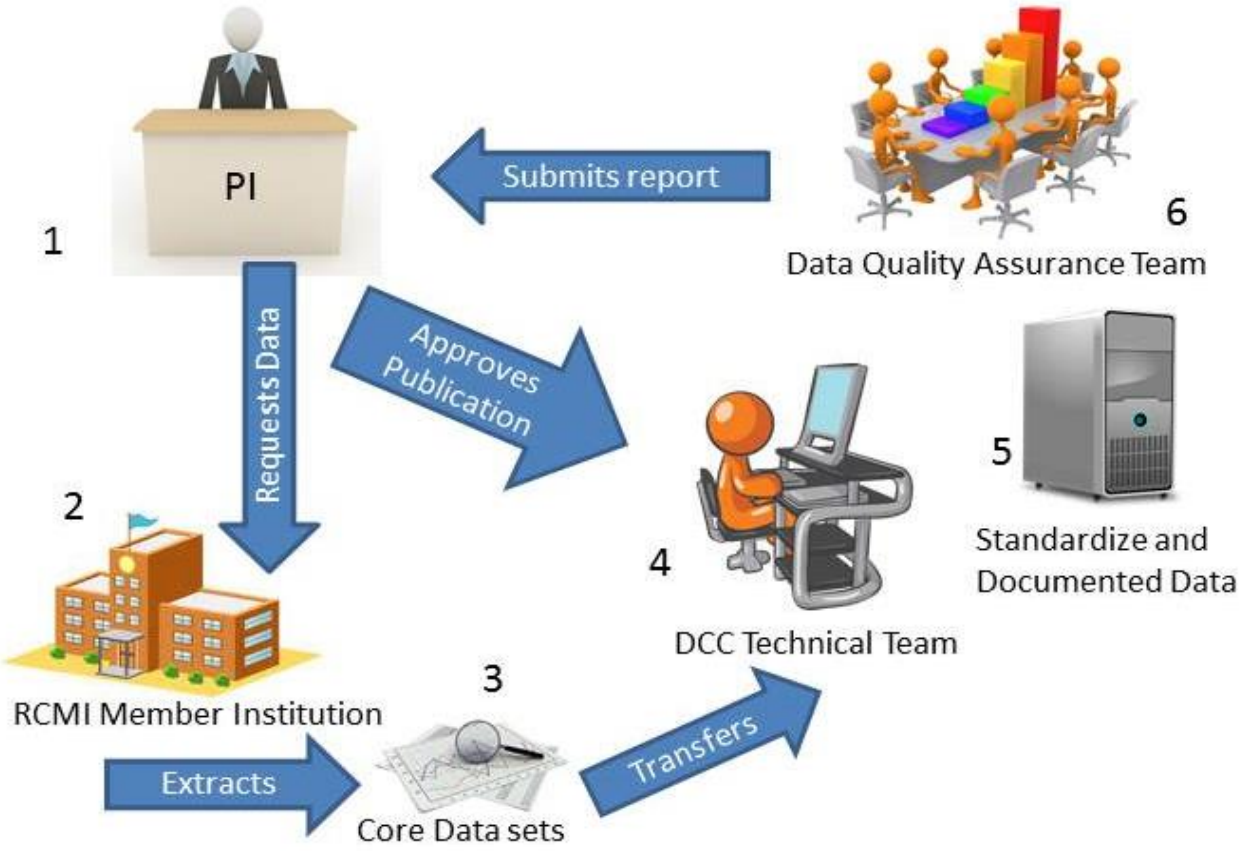
a. Secondary data will be prepared and quality assured by the working group responsible for the specific Network activity, with the involvement of the DCC technical team. The working group will report to RTRN PI, coordinating center directors, and the Steering Committee when the data are available (documented, cleaned, in standard format, and locked for analysis). Within 12 months of data availability or as soon as the primary output from the working group has been submitted for publication (if earlier than 12 months after data availability), the PI will be informed of the readiness of the data for sharing. Following approval by the Steering Committee the data will be made available for public use through licensed access on the RTRN-DCC Data Repository.

b. All Network activities involving primary data collection should ensure that they include a data-sharing plan that is consistent with this policy and with the stated commitment of all RCMI institutions involved. This plan will be reviewed as part of the proposal-approval process. Projects will be required to share data. In general, data should be shared for

public use within 12 months of the completion of data collection, cleaning, and validation, through licensed access on the RTRN-DCC Data Repository. Where specific circumstances require more restrictive access, this should be submitted to the RTRN PI for consideration and appropriate action.

D. Third Party Data. These data are subject to the terms of this policy unless otherwise determined through prior agreement.

Network Core Data Process



1. PI issues a call to Network Member Institutions to submit data in terms of agreed Network membership criteria.
2. RCMI Member Institution responds to call for data.
3. RCMI Member Institution extracts and transfers core minimum dataset to RTRN-DCC technical team.
4. RTRN-DCC Technical team processes, standardizes and documents data received from RCMI Member Institutions, and
5. Produce standardized and documented data products (data sets that are anonymized, uniquely identified and attributed to member institution of origin and the RTRN Network.
6. Prior to publication all data products are submitted to a Data Quality Assurance Team for assessment. This group submits a report to the PI with recommendations.
7. Based on the recommendations from the Data Quality Assurance Team, the PI instructs Technical Group to publish the data product/s on the RTRN Data Repository.

Protection of Human Subjects and Intellectual Property

RTRN recognizes that the rights and privacy of individuals who participate in NIH-sponsored research must be protected at all times, and patentable and other proprietary data should also be protected. In this regard, guidelines provided by the NIH Data Sharing Policy, published in the NIH Guide on February 26, 2003, will be followed (http://grants.nih.gov/grants/policy/data_sharing/). Compliance with these regulations applies to data generated from basic, clinical studies, surveys, and other types of research.

Ownership of Intellectual Property

Ownership of Network-Supported Intellectual Property (NSIP) shall be determined by applicable US law and the policies of NIH and the relevant Participating Institution(s). The Parties agree that the authority and responsibility for making decisions regarding legal protection and commercialization of NSIP shall rest with the owners of the NSIP. Where there are two or more owners of the NSIP, they shall designate an agent to act on their behalf. For greater certainty and without limitation, unless otherwise agreed to in writing on a case-by-case basis by the owners of NSIP, no one other than the owner of NSIPs have any rights in the NSIP, other than the right to a non-exclusive license as provided in the Agreement.

Data Dissemination

Sharing of data generated by RTRN will be carried out in several different ways. The Network will make results available to RCMI scientists interested in conducting health disparities as approved in the Sharing Data Agreement. Conversely, we welcome collaboration with investigators from other NIH programs and non-RCMI institutions who could make use of data, samples, protocols and/or methodologies developed by the Network. In all cases, a Sharing Data Agreement is required.

Guidelines and operating procedures for collecting and distributing data will be developed by the Data Coordinating Center and ratified by the RTRN Steering Committee. Special attention will be given to: (1) understanding what is needed to prepare data for wider distribution and documentation for users; (2) providing stable, reliable, and cost-effective means for distributing data; (3) providing protections for the dataset and technical assistance for requestors. Guidelines will also address the schedule for data sharing; format of final dataset; documentation to be provided by requestor; analytical tools to be provided by DCC, if any; data sharing agreement; available mode(s) of data sharing.

Dissemination of Resources and Final Research Data includes the following:

- Presentations at national scientific meetings
- Publications in peer- review journals
- Webinars sponsored by RTRN
- Short Articles in RTRN Newsletter
- Scientific Highlights on RTRN and RCMI Programs Websites

- Bi-annual NIMHD Grantees Conference
- *eagle-i* platform
- Presentations at community organizations

EFFECTIVE DATE

This Policy shall enter into force as of the date this agreement is approved by RTRN Steering Committee and shall remain in force until June 30, 2022, at which time it will be reviewed by the RTRN Steering Committee and amended as needed.

Document History

Date	Version	Recommendation/Description	Author/Revised by
6/20/2017	2.0	Authorized by Steering Committee Chair after Steering Committee Ratification	Emma Fernández-Repollet, Ph.D. UPR Medical Sciences Campus
6/13/2017	1.2	• Data Categories, page 11 - Line A: Revised to add “when such data are attributed” 2. • Appendix A: General Conditions of use for Agreements, page 19 - Line 1: Revised to add “covered under this policy”	Said Talbi, Ph.D., M.Sc. Jackson State University
4/25/2017	1.1	Participating Institutions, pages 4-9: Updated PI / PD contact information and grant attributions • Appendix A: General Conditions of use for Agreements, page 18, 19 - Item 10 added, a request for exemption of such section(s) should be submitted by the corresponding institutional official to RTRN Research for exemption to be granted. - Item 11 added, Data Sharing RTRN Agreements require approval by the Research Coordinating Center-Implementation Associate Director and ratification by the RTRN Steering Committee before execution. • Revisions to Appendix B-1, SAMPLE Uniform Data Sharing RTRN Agreement, page 22 - Section B.c. Page 25: Revised to add “do not interfere with institutional policies” • Section C, page 26: Confidential information and transfer of material - “Form” was replaced with “the examples”. • Dispute Resolution, Section G. 8, page 20 - Section G.8.b, page 29: Revised to add “unless exempted” to Mediation, page 27 - Section G.8.c, page 29: Revised to add unless institutional policies forbid such arbitration to Arbitration • Appendix B-3, page 35, item 6: SAMPLE Confidentiality Agreement - Revised to add “Disclosures required by state law are allowed”	Marilyn G. Foreman, MD, MS Morehouse School of Medicine Emma Fernández-Repollet, Ph.D. UPR Medical Sciences Campus Robert Kirken University of Texas El Paso Marla Berry, Jerris Hedges, Rory Kaneshiro University of Hawaii
6/1/2015	1.0	Author, Steering Committee Chair	Emma Fernández-Repollet, Ph.D. UPR Medical Sciences Campus

LIST OF APPENDICES

Appendix A

General Conditions of Use for Agreements

1. Data and other material covered under this policy will not be redistributed or sold to other individuals, institutions or organizations without RTRN's formal written agreement. will not be redistributed or sold to other individuals, institutions or organizations without RTRN's formal written agreement.

2. Data originating from a single contributing RCMI member of the RTRN Network may not be analyzed or reported on in isolation without the express permission of the RCMI member concerned.

3. No attempt will be made to re-identify respondents, and there will be no use of the identity of any person or establishment discovered inadvertently. Any such discovery will be reported immediately to RTRN.

4. No attempt will be made to produce links between datasets provided by RTRN or between RTRN data and other datasets that could identify individuals.

5. Any books, articles, conference papers, theses, dissertations, reports or other publications employing data obtained from RTRN will acknowledge the source, in line with the citation requirement provided with the dataset.

6. An electronic copy of all publications based on the provided data will be sent to RTRN.

7. The original collector of the data, RTRN, and the relevant funding agencies, bear no responsibility for the data's use or interpretation or inferences based upon it.

The following applies to restricted licensed access only:

8. The researcher's organization must be identified, as must the principal and other researchers involved in using the data. The principal researcher must sign the license on behalf of the organization. If the principal researcher is not authorized to sign on behalf of the receiving organization, a suitable representative must be identified.

9. The intended use of the data, including a list of expected outputs and the organization's data dissemination policy must be provided.

10. If Institutional Policies are in conflict with any section(s) of the Uniform Data Sharing RTRN Agreement (Appendix B-1) a request for exemption of such section(s) should be submitted by the corresponding institutional official to RTRN Research for exemption to be granted.

11. Data Sharing RTRN Agreements require approval by the Research Coordinating Center-Implementation Associate Director and ratification by the RTRN Steering Committee before execution.

Appendix B-1

SAMPLE Uniform Data Sharing RTRN Agreement

WHEREAS the Network has been selected to be funded under the RCMI Translational Research Network (RTRN) program;

WHEREAS in discharging its obligations under its Notice of Award with the Granting Agency, the Network will support or sponsor certain research activities carried out at Participating Institutions by Network Investigators;

WHEREAS the Funding Agreement obliges the Network to enter into an agreement with Participating Institutions, setting out the obligations of the parties and providing for such matters as reporting requirements, use of research funds, and ownership and exploitation of intellectual property;

NOW THEREFORE IN CONSIDERATION of the premises and of the mutual covenants contained herein, the Parties agree as follows:

1. DEFINITIONS

In this Agreement, the following terms are defined as follows: Data Coordinating Center means the central data facilities of the Network located at Jackson State University.

Agreement means this Uniform Data Sharing RTRN Agreement including all attachments and appendices as may be amended from time to time.

Confidential Information means knowledge, materials, know-how or any proprietary information, whether in electronic, written, graphic or other tangible form and any such oral information that has been reduced to writing within two weeks of its disclosure.

Granting Agency means the National Institute on Minority Health and Health Disparities at the National Institutes of Health (NIH).

Intellectual Property means all materials, concepts, know-how, formulae, inventions, improvements, industrial designs, processes, patterns, machines, manufactures, compositions of matter, compilations of information, patents and patent applications, copyrights, trade secrets, technology, technical information, software, prototypes and specifications, including any rights to apply for protections under statutory proceedings available for those purposes, provided they are capable of protection at law.

RTRN Funds means funds provided to the Network by the Granting Agency, of which are set out in the RTRN Notice of Award.

RTRN Funding Agreement means the agreement entered between the RCMI Institutions and the Network.

Network means RTRN, a U54 program supported by the National Institute on Minority Health and Health Disparities at the National Institutes of Health (NIH).

Network Affiliate means an RCMI Institution, company, government agency or other organization that is involved in a specific aspect of Network research or other Network activity or provides support to the Network and that has been accepted as an Affiliate of the Network by RTRN Senior Management and Steering Committee and that has entered a Network Affiliate agreement with the Network.

Network Funds means all funds managed by the Network, including RTRN Funds and non-RTRN funds provided by Network Affiliates and Network Members and funds provided by other sources in support of the activities of the Network. Network funds result from agreements between the Network and any of the following: Network Affiliates, Network Members and third parties.

Network Host means the Participating Institution or other organization that houses the Administrative Coordinating Center and that has signed the Funding Agreement.

Network Investigator means:

a. a person employed or otherwise given academic status by a Participating RCMI Institution who is responsible for a specific aspect of Network Research; and
b. who has been accepted as an Investigator in the Network by RTRN Senior Management and Steering Committee;

Network Manager means the individual responsible for the general management of the Network's day-to-day operations.

Network Member means an RCMI Participating Institution, the Network Host and any other organization accepted for membership by RTRN Senior Management and Steering Committee.

Network Research means research projects substantially supported by Network Funds and carried out under the supervision of Network Investigators.

Network Strategic Plan means a description of the proposed activities of the Network comprised of two primary elements: the research plan, including its objectives and milestones, its anticipated achievements and the value added of a network approach to the research and research management; and the business management plan outlining the strategic importance of the research to US health and its potential economic and social benefits, the intellectual property management and technology transfer mechanisms, and the details of the proposed management structure.

Network-Supported Intellectual Property (NSIP) means Intellectual Property created or invented during a Network Research project.

Net Revenues means proceeds received from commercialization of Network Supported Intellectual Property (NSIP) minus reimbursement of out-of-pocket expenses incurred in obtaining legal protection for and/or commercialization of the NSIP.

Non-RTRN Funds means funds provided by Network Affiliates, Network Members and by other sources in support of the activities of the Network.

Participating Institution means any university, post-secondary educational institution hospital, institute or other organization eligible to receive research funds from any Granting Agency and that employs or otherwise gives academic status to one or more Network Investigators.

Parties mean the signatories to this Agreement.

Research Coordinating Director means the individual responsible for directing the scientific development of the Network and overseeing Network Research and the Network Strategic Plan.

Technology Transfer Office means the office at the Participating Institution or Network Member where a Network Investigator is employed or holds academic status that has responsibility for commercializing Intellectual Property.

2. OBLIGATIONS OF PARTICIPATING INSTITUTIONS

A. FINANCIAL MANAGEMENT AND REPORTING REQUIREMENTS

Participating Institutions shall hold Network Funds in trust for use by the Network and the Network Investigators in accordance with the Notice of Award, the terms established by the Network, the policies of the Participating Institutions and the requirements of the RTRN Program.

a. Each Participating Institution shall provide to Network Manager at the Administrative Coordinating Center, by June 30 of each year of this Agreement, financial reports for all Network Funds they receive in accordance with the requirements of the Network and the RTRN Program.

b. Each Participating Institution receiving Network Funds shall:

i. ensure that adequate financial controls consistent with the rules and guidelines of the RTRN Program and NIH rules and regulations are maintained with respect to Network Funds;

ii. keep proper accounts and records of all eligible expenditures;

iii. provide the Administrative Coordinating Center with the name and address of the person at the Participating Institution responsible for the administration and accounting of

Network Funds and the name and address of the responsible person at the Technology Transfer Office;

iv. work in concert with the owners and inventors of the NSIP, the inventor's employer and the Network, in the commercialization of NSIP;

v. provide their Network Investigators with sufficient space, time and institutional support to allow them to contribute to Network Research;

vi. promptly notify the Administrative Coordinating Center if a Network Investigator ceases to be employed by a Participating Institution or otherwise ceases to hold academic status at that Institution;

B. CONFIDENTIAL INFORMATION AND MATERIAL TRANSFER

In carrying out the activities contemplated by this Agreement, it is anticipated that the Participating Institutions may disclose certain information or material which is considered by the disclosing party to be confidential. Where such information is disclosed or material is transferred, it shall be substantially in accordance with guidelines related to the Confidentiality Agreement (Appendix B-3) and Material Transfer Agreement (Appendix B-4).

C. OTHER REQUIREMENTS

a. Each Participating Institution shall obtain in writing an acknowledgment, from each of their respective Network Investigators that he or she understands and agrees to be bound by the provisions entitled "Obligations of Network Investigators" set out in Article 3 of this Agreement;

b. Each Participating Institution shall use its best efforts to ensure that the Network Investigator has complied with the requirement that students and all others members of the Network Investigator's research team have entered agreements containing substantially similar terms to those governing the Network Investigator set out in this Agreement;

c. Each Participating Institution shall ensure that Network Investigators obtain appropriate certification and/or approval regarding use of humans, animals and/or biohazards in the conduct of Network Research in accordance with the requirements of the RTRN Program and the Funding Agency (NIH);

d. Research involving human subjects shall meet the requirements for Ethical Conduct of Research Involving Humans;

e. Research requiring the use of animals shall be conducted in accordance with the policies and guidelines of NIH Animal Care: Guide to the Care and Use of Experimental Animals;

f. Research involving biohazards shall be conducted in accordance with the requirements of the state and federal Laboratory Biosafety Guidelines.

3. OBLIGATIONS OF NETWORK INVESTIGATORS

In signing the Acknowledgement form, a Network Investigator agrees as follows:

A. PUBLICATIONS

In all presentations and publications of results of Network Research, the Network Investigator shall acknowledge the author's participation in the Network and the support of the RTRN Program and NIMHD, and shall also refer to industrial support where appropriate (subject to written permission to do so where appropriate).

B. DISCLOSURE AND COMMERCIALIZATION OF NSIP

a. The Network Investigator shall promptly disclose in writing to the Network Manager and to the Technology Transfer Office, any results of Network Research that the Network Investigator believes have the potential to be commercialized;

b. The Network Investigator shall withhold publication for the longer of 90 days or for such period as is provided by the policies of his/her Participating Institution, any such material pending evaluation by the Network Manager and/or his/her delegate and the Technology Transfer Office of his/her Participating Institution to determine whether contents contain patentable, commercializable or confidential information. For greater clarity Network Investigators shall not be restricted from presenting at symposia, national, or regional professional meetings, or from publishing in abstracts, journals, theses, or dissertations, or otherwise, whether in printed or in electronic media, methods and results of research carried out pursuant to this Network Agreement, except where such publication or presentation would result in the public disclosure of RTRN or Confidential Information.

c. Furthermore, upon request by the Network or the Participating Institution, the Network Investigator shall further delay publication of RTRN data for up to 6 months to provide time for the Network or the Participating Institution to seek patent protection for RTRN. The Network Investigator will work with the institutional Technology Transfer Office to ensure that any such delays do not interfere with institutional policies, a student's thesis defense or the graduation of the student.

d. The Network Investigator shall promptly disclose in writing to his/her Participating Institution, and to the Administrative Coordinating Center any conflict of interest that may arise pursuant to the terms of Section D of this Article 3.

e. The Network Investigator shall promptly disclose in writing to the Network Manager and to the Technology Transfer Office existing Intellectual Property and any prior art which could limit the extent to which proposed and/or ongoing Network Research could be commercialized.

C. CONFIDENTIAL INFORMATION AND TRANSFER OF MATERIAL

The Network Investigator shall ensure that the appropriate agreements concerning the disclosure of Confidential Information and the transfer of biological and other materials are entered prior to any disclosure of Confidential Information or transfer of material by the Network Investigator. Where such information is disclosed or material is transferred, it shall be substantially in accordance with the examples. (Confidentiality Agreement attached as Appendix B-3 or the Material Transfer Agreement attached as Appendix B-4).

D. CONFLICT OF INTEREST AND RESEARCH ETHICS

a. The Network Investigator shall abide by the Policy Statement on Integrity in Research governing the use of NIH grant funds and the conduct of research.

b. Each Network Investigator shall abide by the provisions of his/her Participating Institution's policies and guidelines with respect to conflict of interest and conflict of commitment and by the provisions of the NIH Conflict of Interest Policy. To the extent that there may be a conflict between these policies, the more stringent requirements shall prevail.

c. The Network Investigator shall be responsible for ensuring that appropriate certification and/or institutional approval is obtained for their Network Research that involves human subjects, or requires the use of animals or biohazards.

E. RECORDS AND REPORTS

a. The Network Investigator shall submit research progress reports to the Administrative Centre as required by the Network;

b. The Network Investigator shall ensure that students and all other members of his or her research team have entered agreements containing substantially similar terms to those governing the Network Investigator set out in this Agreement;

c. The Network Investigator shall ensure that students and all other members of his or her research team maintain effective best practices record keeping for experiments carried out as part of Network Research.

F. OTHER OBLIGATIONS

a. The Network Investigator shall use reasonable efforts to attract complementary research funding;

b. The Network Investigator shall work in concert with the Network, the Participating Institutions, Network Affiliates and other inventors in the commercialization of Network-Supported Intellectual Property including, but not limited to, the prosecution of patents,

all in accordance with Articles 5 (Ownership of Intellectual Property) and 6 (Principles of Commercialization of Intellectual Property).

c. Participate on Network committees and in other Network activities as required.

G. TERMINATION OF PROJECT FUNDING

Where the Network determines that a Network Investigator has failed to comply with the duties and responsibilities set out in this Agreement, it shall promptly notify the Participating Institution and the Network Investigator. The Network Investigator shall have thirty (30) days within which to remedy the failure, failing which the Network may terminate funding of the Network Research carried out by the Network Investigator. Notwithstanding the termination of funding, the Network Investigator will co-operate with the Network to ensure an orderly transfer of any data/materials provided, share any new data obtained, and phase-out of activities and shall continue to be bound by the provisions of this agreement governing intellectual property, publication, confidentiality and any other provisions which are necessary for the Network to fulfill its obligations associated with the RTRN Program.

4. DISCLAIMERS OF WARRANTY AND LIABILITY

Each Party to this Agreement acknowledges that all research results, including information, Intellectual Property and other tangible and intangible materials that it may receive pursuant to this Agreement are to be used with caution and prudence, since all of their characteristics are not known. Each party disclaims all liability for any damages however arising from the use of such research results. Each Party further acknowledges that such research results, information, Intellectual Property and other tangible or intangible materials are provided without warranty of merchantability or fitness for a particular purpose or any other warranty of any sort, express or implied, and that the provider makes no representations that the use of the same will not infringe any patent or other proprietary right. This Article survives the provisions of Article 10 of this Agreement (Withdrawal).

5. OWNERSHIP OF INTELLECTUAL PROPERTY

Ownership of Network-Supported Intellectual Property (NSIP) shall be determined by applicable US law and the policies of NIH and the relevant Participating Institution(s). The Parties agree that the authority and responsibility for making decisions about legal protection and commercialization of NSIP shall rest with the owners of the NSIP. Where there are two or more owners of the NSIP, they shall designate an agent to act on their behalf. For greater certainty and without limitation, unless otherwise agreed to in writing on a case-by-case basis by the owners of NSIP, no one other than the owners of NSIP shall have any rights in the NSIP, other than the right to a non-exclusive license provided for in clause (b) of Article 6 of this Agreement.

6. PRINCIPLES OF COMMMERCIALIZATION OF INTELLECTUAL PROPERTY

a. Upon written request to the owner(s) of the NSIP, the Network Members shall be offered a non-transferable, non-exclusive, royalty-free, perpetual license to use and modify all NSIP solely for research and educational purposes if the terms and conditions of such license will not interfere with efforts to commercialize the NSIP.

b. Within 30 days after the receipt of a written disclosure, the NSIP owner(s), the inventor's employer or the Network shall call a meeting of all interested parties to discuss the history of support, the potential for commercialization, a plan for management, share of returns and commercialization of the intellectual property.

7. SHARING OF NET REVENUES

a. The owner, the inventor, the inventor's employer, the Network and the relevant Network Affiliate or Network Member, shall be entitled to a share of the Net Revenues commensurate with their contributions related to the NSIP, in accordance with the applicable Participating Institution's official policies, those of other Network Members as appropriate, as well as the terms of any relevant Network Affiliate agreement.

b. The parties shall negotiate the terms in good faith.

8. DISPUTE RESOLUTION

a) Consultation/Negotiation. In the event of a controversy or dispute between or among any Parties arising out of or in connection with this Agreement or regarding its interpretation or operation, the disputing Parties agree to shall use their best efforts to resolve the dispute amicably.

b) Mediation. If the Parties are unable to resolve their dispute within sixty (60) days after beginning the consultation/negotiation process, any Party to the dispute may serve written notice on the other Party(s) requiring that they submit the dispute to non-binding mediation, unless exempted. The Parties shall mutually agree on a single mediator to mediate the dispute in accordance with mediation procedures suggested by the mediator and agreed to by the Parties. The Parties agree to use best efforts to participate in the mediation process and attempt to resolve their dispute. Each party shall pay its own costs and an equal share of all other costs of the mediation.

c) Arbitration. If the mediation fails to resolve the dispute within 60 days following the day the mediator is appointed, or if one Party refuses to cooperate or participate in good faith in the mediation process, any Party to the dispute serve written notice on the other Parties that the dispute be submitted to binding arbitration, unless institutional policies forbid such arbitration, in the following manner:

i. The Parties shall mutually agree on a single arbitrator to adjudicate the dispute. If the Parties cannot agree on a single arbitrator within fifteen (15) days of receipt of the written

notice requiring arbitration, they shall each appoint a single arbitrator and those arbitrators shall have a further fifteen (15) days to select a third person who will serve as chair of the arbitral panel.

ii. Unless otherwise agreed to by the parties, the arbitration shall be conducted in English and per the governing law of this Agreement and in accordance with arbitral procedures in place in that jurisdiction.

iii. The arbitration shall be carried out no later than sixty (60) days from appointment of the single arbitrator or chair of the arbitral panel, as the case may be.

iv. Unless the Parties to the dispute otherwise agree, the arbitration shall be held in the City where the Network Host is located.

v. Each party shall pay its own costs and an equal share of all other costs of the arbitration.

vi. The award rendered by the arbitration shall be final and binding on all Parties and may be entered as an order in any court having jurisdiction. This Article survives the provisions of Article 9 of this Agreement (Withdrawal).

9. WITHDRAWAL FROM AGREEMENT

a. Voluntary Withdrawal: A Participating Institution shall be entitled to withdraw from this Agreement upon ninety (90) days written notice to the Principal Investigator and to the Director of the Research Coordinating Center.

b. Involuntary Withdrawal: Where the Network determines on the basis of at least a two-thirds majority vote of the Steering Committee that a Participating Institution has failed to comply with the duties and responsibilities set out in this Agreement, it shall promptly notify the Participating Institution(s) of the particulars. The Participating Institution shall have thirty (30) days within which to remedy the failure, failing which the Participating Institution may be deemed to have withdrawn from this Agreement.

c. Consequences of Withdrawal: Upon the effective date of withdrawal of a Participating Institution, the withdrawing Participating Institution shall submit to the Network a full accounting and all unused and uncommitted funds advanced by the Network. The withdrawing Participating Institution and Network Investigator(s) will cooperate with the Network to ensure an orderly transfer of responsibilities and phase-out of activities.

Upon the withdrawal of a Participating Institution, that Institution’s Network Investigators will no longer be able to receive Network Funds through that Participating Institution.

Notwithstanding withdrawal from this Agreement, the Participating Institution and the Network Investigator shall continue to be bound by the provisions of this Agreement governing intellectual property, publication, confidentiality, return of data and materials,and any other provisions which are necessary for the Network to fulfill its obligations to the RTRN Program.

Appendix B-2

SAMPLE Micro Data Set Submission Agreement between RCMI Submitting Institution and RTRN

Agreement between [RCMI institution] and RTRN regarding the submission and use of micro data

A. This agreement relates to the following micro datasets:

Number	Data Set	Access Level

B. Terms of the agreement:

As the owner of the copyright in the data listed in section A, or as duly authorized by the owner of the copyright in the data, the representative of [providing RCMI institution] grants RTRN permission for the datasets listed in section A to be used by RTRN, subject to the following conditions:

1. Micro data (including subsets of the datasets) and copyrighted materials provided by the [RCMI institution] will not be redistributed or sold to other individuals, institutions or organizations without the [RCMI institution]'s written agreement. Non-copyrighted materials which do not contain micro data (such as survey questionnaires, manuals, codebooks, or data dictionaries) may be distributed without further authorization. The ownership of all materials provided by the [RCMI institution] remains with the [RCMI institution].

2. Data will be used for statistical and scientific research purposes only. They will be employed solely for reporting aggregated information, including modelling, and not for investigating specific individuals or organizations.

3. No attempt will be made to re-identify respondents, and there will be no use of the identity of any person or establishment discovered inadvertently. Any such discovery will be reported immediately to the [RCMI institution].

4. No attempt will be made to produce links between datasets provided by the [RCMI institution] or between [RCMI institution] data and other datasets that could identify individuals or organizations.

5. Any books, articles, conference papers, theses, dissertations, reports or other publications employing data obtained from the [RCMI institution] will cite the source, in line with the citation requirement provided with the dataset.

6. An electronic copy of all publications based on the requested data will be sent to the [RCMI institution].

7. The [RCMI institution] and the relevant funding agencies bear no responsibility the data's use or for interpretation or inferences based upon it.

8. Data will be stored in a secure environment, with adequate access restrictions at RTRN-Data Coordinating Center (DCC). The [RCMI institution] may at any time request information on the storage and dissemination facilities in place.

9. RTRN-DCC will provide an annual report on uses and users of the listed micro datasets to the [RCMI institution], with information on the number of researchers having accessed each dataset, and on the output of this research.

10. This access is granted for the duration of the [RCMI institution] membership of the RTRN Network.

C. Confidentiality:

The [RCMI institution] confirms that there are no ethical or legal obligations that prevent the use and sharing of the micro data sets listed in A, at the indicated access level.

D. Communications:

RTRN-DCC will appoint a contact person who will act as focal person for this agreement. Should the focal person be replaced, RTRN will communicate the name and coordinates of the new contact person to the [RCMI institution]. Communications for administrative and procedural purposes may be made by email, fax or letter as follows:

Communications made by [RCMI institution] to RTRN will be directed to:

Name of contact person:
Title of contact person:
Address of RTRN recipient:
Email:
Tel:
Fax:

Communications made by RTRN to [RCMI Institution] will be directed to:

Name of contact person:
Title of contact person:
Address of the recipient RCMI institution:
Email:
Tel:
Fax:

D. Signatories

The following signatories have read and agree with the Agreement as presented above:

Representative of the [RCMI Institution]

Name _____

Signature _____ Date _____

Representative of RTRN

Name _____

Signature _____ Date _____

Appendix B-3

SAMPLE Confidentiality Agreement

THIS INTER-INSTITUTIONAL AGREEMENT is made by and between the RCMI Translational Research Network (RTRN), with its Administrative Coordinating Center located at Morehouse School of Medicine in Atlanta, GA, represented in this act by its Principal Investigator _____ , (hereinafter referred to as "RTRN") and _____, represented in this act by its_____, _____ , (hereinafter referred to as the "Network Affiliate").

WHEREAS the Parties intend to cooperate in utilizing databases at RTRN-DCC Data Repository for the performance of experimental, developmental or research work in _____ (hereinafter the "Research Technology"); and

WHEREAS information about the Research Technology, which is proprietary and confidential, including, but not limited to discoveries, inventions, improvements, know-how, manufacturing techniques, specifications, technical data, engineering data, formulae, recipes, process technologies, business plans, marketing and economic data and other related information (hereinafter "Confidential Information") will be transmitted between the Parties;

THEREFORE, in consideration of the mutual disclosures between the Parties, they hereby agree to the following terms and conditions:

1. The Parties may disclose to each other Confidential Information related to the Research Subject. The Party receiving information related to the Research Subject may use such information in connection with the performance of experimental, developmental or research work in the Research Subject. Ownership of any intellectual property rights including, without limitation, any patents or copyrights, derived or resulting from information disclosed under this Agreement shall be determined pursuant to the laws governing such intellectual property.

2. RTRN will own all right, title and interest in and to any invention involving Research Technology, whether or not patentable, invented solely by RTRN investigators. RTRN will own all right, title and interest in and to any invention involving Research Technology, whether or not patentable, invented solely by employees of RTRN. Right, title and interest in and on to inventions involving Research Technology, whether or not patentable, invented jointly by employees of both parties will be owned jointly by the parties. For Joint Inventions, the parties will negotiate in good faith a separate inter-institutional agreement detailing, among other things, which party will take the lead role in preparing, filing and prosecuting patents that originate from the Research

Technology and take the lead role in business development activities. They will also negotiate in good faith and according to their respective institutional policies, out-of-pocket patent costs and other related issues. If any of the Parties elect to file a patent application in any country related to the Research Technology, the Party filing such patent application shall notify the other Party to this Agreement within thirty (30) days of such filing.

3. A confidential relationship shall arise between the Parties, and each Party agrees to hold in confidence all Confidential Information disclosed to it by the other and not to disclose such Confidential Information to anyone except such of its employees or personnel as may be necessary and not to use such Confidential Information for a purpose not covered by this Agreement, unless:

   a. Such confidential Information is a part of the public domain prior to the date first hereinabove; or

   b. Such Confidential Information becomes a part of the public domain not due to some unauthorized act by or omission of the Party receiving the Confidential Information after this Agreement is executed; or

   c. The Party receiving the Confidential Information can demonstrate that it or an affiliate or a subsidiary independently developed such Confidential Information prior to the date first written hereinabove; or

   d. Such Confidential Information is disclosed to the Party receiving the Confidential Information by a third party who has the right to make such disclosure; or

   e. Such Confidential Information is required to be disclosed to a third party by applicable laws or out of court proceedings.

4. The Parties shall use at least a reasonable degree of care to preserve the confidentiality of the Confidential Information and shall use at least the same efforts to preserve the confidentiality of Confidential Information received from the other Party as they would use to preserve the confidentiality of their own Confidential Information.

5. The Confidential Information referred to hereunder will be furnished to the Parties for purposes of conducting experimental, developmental and research work in the Research Subject and for no other purpose.

6. The Parties will permit their employees, students and any other personnel affiliated therewith to have access to Confidential Information received from the other Party only on a need-to-know basis, and only if they agree to observe the nondisclosure and non-use obligations contained in this Agreement. Disclosures required by state law are allowed. Each person that receives Confidential Information shall sign an acknowledgement of this Agreement.

7. Upon the conclusion of the Parties' collaboration on the Research Subject, each Party shall return to the other all written material and/or prototypes and/or samples it received. The return of the material shall not affect the obligations of each Party to treat the Confidential Information disclosed to it as confidential and not to use same, which confidentiality shall continue for a period of three (3) years from receipt of the Confidential Information.

8. This Agreement shall be binding upon and inure to the benefit of the successors and assigns of the Parties hereto, but neither of the Parties hereto shall assign this Agreement without the prior written consent of the other Party.

9. No modification or waiver of any of the provisions of this Agreement shall be valid unless in writing and signed by the Parties hereto.

10. This Agreement shall remain in force for a period of five (5) years or until the Parties' collaboration on the Research Subject terminate, whichever occurs later.

We hereby acknowledge and agree to abide by the terms of the attached Agreement.

ACCEPTED AND AGREED TO BY:

Representative of the [RCMI Institution or Network Affiliate]

Name _____

Signature _____ Date _____

Representative of RTRN

Name _____

Signature _____ Date _____

Appendix B-4

SAMPLE Material Transfer Agreement

In 1995, the NIH published the first and only widely accepted model agreements for transfers of materials, the Simple Letter Agreement for the Transfer of Biological Material (NIH SLA) and the Uniform Biological Material Transfer Agreement (UBMTA), along with guidance for the transfers of research tools. The NIH called on grantees to ensure that unique research resources arising from NIH-funded research are made available to the scientific research community using either no formal agreement or under terms or agreements that are no more restrictive than the UBMTA for most materials, a call that has been renewed by the NRC.

If an MTA is needed, the simplest standard agreement is recommended. In 1999, NIH published the Simple Letter MTA template, and has recommended it for transfer of many types of materials. It is accepted by almost all universities. NIH also has two other simple MTAs for different classes of materials, living organisms and human tissues and specimens (see below).

NIH Simple Letter Agreement for the Transfer of Materials

In response to RECIPIENT's request for the MATERIAL _____
the PROVIDER asks that the RECIPIENT and the RECIPIENT SCIENTIST agree to the following before the RECIPIENT receives the MATERIAL:

1. The above MATERIAL is the property of the PROVIDER and is made available as a service to the research community.
2. **THIS MATERIAL IS NOT FOR USE IN HUMAN SUBJECTS.**
3. The MATERIAL will be used for teaching or not-for-profit research purposes only.
4. The MATERIAL will not be further distributed to others without the PROVIDER's written consent. The RECIPIENT shall refer any request for the MATERIAL to the PROVIDER. To the extent supplies are available, the PROVIDER or the PROVIDER SCIENTIST agree to make the MATERIAL available, under a separate Simple Letter Agreement to other scientists for teaching or not-for-profit research purposes only.
5. The RECIPIENT agrees to acknowledge the source of the MATERIAL in any publications reporting use of it.
6. Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. THE PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Unless prohibited by law,

Recipient assumes all liability for claims for damages against it by third parties which may arise from the use, storage or disposal of the Material except that, to the extent permitted by law, the Provider shall be liable to the Recipient when the damage is caused by the gross negligence or willful misconduct of the Provider.
7. The RECIPIENT agrees to use the MATERIAL in compliance with all applicable statutes and regulations.
8. The MATERIAL is provided at no cost, or with an optional transmittal fee solely to reimburse the PROVIDER for its preparation and distribution costs. If a fee is requested, the amount will be indicated here: _____.

The PROVIDER, RECIPIENT and RECIPIENT SCIENTIST must sign both copies of this letter and return one signed copy to the PROVIDER. The PROVIDER will then send the MATERIAL.

PROVIDER INFORMATION and AUTHORIZED SIGNATURE

Provider Scientist:_____

Provider Organization: _____

Address:_____

Name of Authorized Official: _____

Title of Authorized Official:_____

Certification of Authorized Official: This Simple Letter Agreement has □ / has not □ [check one] been modified. If modified, the modifications are attached.

_____ _____
Signature of Authorized Official Date

RECIPIENT INFORMATION and AUTHORIZED SIGNATURE

Recipient Scientist: _____

Recipient Organization: _____

Address: _____

Name of Authorized Official: _____

Title of Authorized Official: _____

Official:_____

Signature of Authorized Official:_____

Date: _____

Certification of Recipient Scientist: I have read and understood the conditions outlined in this Agreement and I agree to abide by them in the receipt and use of the MATERIAL.

Recipient Scientist: _____

Date: _____

Additional Resources:

To encourage the use of these standardized documents, the Association of University Technology Managers (AUTM) has developed a toolkit aimed at encouraging the use of standard agreements. The kit contains a decision tree to assist technology-transfer professionals in selecting an agreement appropriate for the transfer, incorporates easy-to-use fillable forms for existing NIH templates, and a new set of model agreements modifying the UBMTA to make it more adaptable to a wider variety of situations. This resource is also recommended to RCMI Member Institutions.

References:

http://www.autm.net/resources-surveys/material-transfer-agreements/mta-toolkit-selecting-mta/

http://www.autm.net/resources-surveys/material-transfer-agreements/

APPENDIX C. References

1. FINAL NIH STATEMENT ON SHARING RESEARCH DATA / RELEASE DATE: February 26, 2003 / NOTICE: NOT-OD-03-032
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

2. NIH Data Sharing Brochure (PDF - 244 KB) – (05/20/2003)
http://grants.nih.gov/grants/policy/data_sharing/data_sharing_brochure.pdf

3. NIH Data Sharing Policy and Implementation Guidance (Updated: March 5, 2003)
http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm

4. Data Sharing Regulations/Policy/Guidance Chart for NIH Awards (08/30/2006) - (MS Word - 58 KB) - This chart is designed as a quick guide only for the purpose of identifying various data sharing regulation/policy/guidance documents applicable to NIH funding. http://grants.nih.gov/grants/policy/data_sharing/

5. Frequently Asked Questions-Data Sharing\ (Last Revised: February 16, 2004).
http://grants.nih.gov/grants/policy/data_sharing/data_sharing_faqs.htm

6. Other Data Sharing Documents and Resources (Updated: February 19, 2004)
http://grants.nih.gov/grants/policy/data_sharing/data_sharing_resources.htm

7. NIH Guidance on Consent for Future Research Use and Broad Sharing of Human Genomic and Phenotypic Data Subject to the NIH Genomic Data Sharing Policy (July 13, 2015)
http://gds.nih.gov/pdf/NIH_guidance_elements_consent_under_gds_policy.pdf.

8. Table of NIH Data Sharing Policies
https://www.nlm.nih.gov/NIHbmic/nih_data_sharing_policies.html
updated 10/21/2014
accessed 5/12/2017

9. NIH Sharing Policies and Related Guidance on NIH Funded Research Resources
https://grants.nih.gov/policy/sharing.htm
updated 8/29/2016
accessed 5/12/2017