I. Purpose

The purpose of this Policy is to provide additional information and direction about the applicable Medical Center policies that govern the appropriate access, use and sharing of data used in research.

Children's Hospital of Chicago Medical Center (the "Medical Center") Administrative Policies explain that employees and staff members, including individual researchers, have certain rights and responsibilities concerning Research Confidential Information protection and stewardship. This Policy provides additional information on the basis of data ownership, and the standards for the collection, protection and retention of data, in addition to requirements for data access. Furthermore, this Policy outlines the process for transfer of Research Confidential Information in the event a researcher leaves the Stanley Manne Children's Research Institute (Manne Research Institute).

For information on the ownership of intellectual property, see the Medical Center's *Intellectual Property and Technology Transfer* Policy.

This Policy does not override any Medical Center Administrative Policy. If there is a conflict the Administrative Policy will prevail.

II. Definitions

Data Trustee: Pursuant to the Medical Center's *Classification and Handling of Information* Policy, the Data Trustee with respect to Research Confidential Information shall be the Principal Investigator responsible for the study to which the information pertains.

Research Confidential Information: Refers to unpublished Research Confidential Information and related documents which, if disclosed, could result in adverse impact or compromise the reputation of the Medical Center. Research Confidential Information includes, but is not limited to:

i. Non-patient identifiable Research Confidential Information derived from Patient Confidential Information and capable of being re-identified by authorized individuals
    a. In the event such information is re-identified, it shall be reclassified as Patient Confidential Information and handled accordingly. The Medical Center's *Classification and Handling of Information* and Health Insurance Portability and Accountability Act (HIPAA) *Privacy and Security* Policies apply.
ii. Information derived from non-patient research, such as research on Medical Center staff

iii. Cell lines derived from patients or other sources
iv. De-identified, aggregate medical information, including diagnoses, results of evaluations and treatments which may be consolidated with similar data from other institutions.
v. Animal models of disease

Furthermore, this Policy explains that all information in whatever form (*e.g.,* both physical and electronic) collected and/or generated in the course of a research project conducted at the Medical Center, under the auspices of the Medical Center, or with Medical Center resources is also considered Research Confidential Information. This includes original and derivatives of Research Confidential Information, including recordings of such data. Additional examples of Research Confidential Information include, but are not limited to:

- Data, analytical programs, procedures, and records necessary for the reconstruction and evaluation of the results of research;
- Data resulting from computational processes and modeling;
- Data contained in laboratory notebooks;
- Histological preparations;
- Data collected using instrumentation or systems and stored in an electronic format including digital images; or
- De-identified case report forms and source documentation for human participant research studies.

Records: Pursuant to the Medical Center's *Record Retention and Disposal* Policy, records include "all information relating to the Medical Center's operations and activities that the Medical Center is required to retain by applicable law, rule or regulation, or that it is important to retain for business reasons, however created, recorded, produced or stored, and whether reduced to hard copy (for example film or paper) or that can be retrieved from electronic or other media (such as computer drives, disks, chips, PDA-type devices and accessories, thumb drives, etc.). 'Records' also include medical or patient records and email communications or documents that can be transmitted electronically."[5]

Principal Investigator: The Investigator who has primary responsibility within the Medical Center for the design, conduct, and reporting of research.

III. Policy Statements

A. Ownership and Responsibilities

Pursuant to the Medical Center Administrative Policies, the Medical Center owns the Research Confidential Information for projects conducted by Medical Center employees, agents and staff, at the Medical Center, under the auspices of the Medical Center or with Medical Center resources. The Medical Center as the owner of Research Confidential Information, and the Principal Investigators (PIs) as Data Trustees, must meet the requirements of sponsors, good management practice and practical considerations necessitate that the Medical Center and PIs act in partnership to fulfill these obligations.

As Data Trustees of Research Confidential Information, PIs and other study personnel granted access are stewards of Research Confidential Information. The PI is responsible to the Medical Center for the protection and stewardship of Research Confidential Information.

The collection, retention, and sharing of Research Confidential Information that incorporates individually-identifiable patient information must comply with all applicable HIPAA *Privacy and Security* Policies, including privacy and information security standards.

Research Confidential Information are to be accessible to members of the Medical Center community, external collaborators and others as appropriate and authorized by study protocols and/or agreements (*e.g.,* for patent applications or journal submissions). Where necessary to assure needed and appropriate access (*e.g.,* for research misconduct investigations), the Medical Center reserves the right to take custody of Research Confidential Information in a manner specified by the Chief Research Officer.

Medical Center's rights and responsibilities concerning research confidential and private data include, but are not limited to:

1. Ensuring compliance with the terms of sponsored project agreements;
2. Ensuring the appropriate use of project resources, *e.g.*, animals, human participants, recombinant DNA, biological agents, radioactive materials, etc.;
3. Protecting the rights of Lurie Children's/Manne Research Institute researchers, including, but not limited to, their rights to access to data from research in which they participated and for which authorization has been obtained when required;
4. Safeguarding and securing intellectual property rights;
5. Facilitating the investigation of charges, such as research misconduct or conflict of interest;
6. Ensuring the proper mechanisms are in place to assist all Medical Center

staff with maintaining the confidentiality of Research Confidential Information; and
7. Maintaining a compliance program to support Medical Center staff and employees compliance with applicable state and federal laws and regulations.

The PI's responsibilities concerning Research Confidential Information include, but are not limited to:

1. Ensuring proper management and retention of Research Confidential Information in accordance with this Policy;
2. Establishing and maintaining appropriate procedures for the protection of Research Confidential Information and other essential records, particularly for long-term research projects;
3. Ensuring compliance with sponsored project agreements and program requirements;
4. Maintaining confidentiality of Research Confidential Information, where appropriate; and
5. Being knowledgeable of and complying with applicable Medical Center policies, and state and federal laws and regulations.

B. Data Retention

Research Confidential Information must be retained in accordance with the Medical Center's *Record Retention and Disposal* Policy and the *CFR 200.333 Retention Requirements for Records*. In general, this policy requires retention for a for a minimum of three years after the financial report for the project period has been submitted or, for non-sponsored projects, a minimum of three years after the project has ended and, if applicable, the budget reconciled. The "Record Retention and Disposal" Policy, Intellectual Property and Technology Transfer Policy and other applicable Administrative policies further provide that any of the following circumstances may justify longer periods of retention:

1. Research Confidential Information must be kept for as long as may be necessary to protect any intellectual property resulting from the work;
2. If litigation or other dispute resolution, claims, financial management review, or audit related to the research project is started before the expiration of the three-year period, or commenced after the three-year period but the relevant data and records have not been destroyed, the

Research Confidential Information and other project records must be retained until all such litigation/dispute resolution, claims, financial management review, or audit findings involving the records have been resolved and final action taken;

3. If any charges regarding the research arise, such as allegations of research misconduct, Research Confidential Information must be retained consistent with the Medical Center's *Record Retention and Disposal* Policy or as otherwise instructed by Medical Center's Office for Corporate Compliance, Office for Research Integrity and Compliance, or Office of General Counsel; If a student is involved, Research Confidential Information must be retained at least until the student's degree is awarded (or the student otherwise leaves their educational program) and any resulting papers are published.
4. When research is funded by an award to or contract with the Medical Center that includes specific provision(s) regarding ownership, retention of, and access to technical data, the provision(s) of that agreement will be in accordance with the Intellectual Property and Technology Transfer Policy
5. Research Confidential Information from human participant research studies must be maintained consistent with the Manne Research Institute *Research Compliance Program Manual* and Medical Center's *Record Retention and Disposal* Policy;
6. If other regulations, federal oversight, sponsor policies or guidelines, journal publication guidelines, or other Medical Center policies require longer retention, all applicable sources must be reviewed and the Research Confidential Information must be kept for the longest period of time applicable.

After the period of retention specified in the *Record Retention and Disposal* Policy, Research Confidential Information for projects continuing after a sponsored award may be retained by the PI. Destruction of Research Confidential Information must follow applicable federal regulations, Medical Center policies on record retention and data disposal, sponsor requirements, and other applicable guidelines. Retained Research Confidential Information will remain under the ownership and auspices of the Medical Center.

Research Confidential Information normally will be retained in the laboratory where they are produced. Please refer to the *Record Retention and Disposal* Policy for additional guidance on responsibilities related to the retention of Research Confidential Information

and records.

C. Access to Data in the Event a Researcher Leaves the Medical Center

When individuals other than the PI involved in research projects at Medical Center leave the institution, they may request to take copies of Research Confidential Information for projects on which they have worked, subject to permissions and relevant confidentiality restrictions and the terms of an executed Data Use Agreement or other appropriate agreement. However, original data will be retained at Medical Center by the PI.

If the PI leaves the Medical Center and desires for certain activities of a research project which is to be moved to another institution, access to specified Research Confidential Information may be authorized from the Medical Center to the PI's new institution upon request from the PI, subject to:

a) confirmation that there are no legal or contractual prohibitions on the use or disclosure of the specified data by the other institution;
b) the prior written approval of the Chief Research Officer;
c) written agreement from the PI's new institution that guarantees:
(1) its acceptance of ongoing custodial responsibilities for the data and
(2) the Medical Center maintaining ownership of the original Research Confidential Information;
d) relevant confidentiality restrictions, where appropriate; and
e) for requests involving transfer of research materials, a written agreement with the transferee institution specifically governing such materials and their maintenance and use, intellectual property resulting therefrom, and any other conditions required by the Medical Center in exchange for the transfer. The Office for Sponsored Programs should be contacted to coordinate the sharing of data or materials to another institution, in consultation with the Privacy Office, Legal Department and Information Security Office.

For additional information about transferring clinical trial records that are subject to federal requirements, please refer to the guidance of the National Institutes of Health (NIH) available at https://prsinfo.clinicaltrials.gov/prs-users-guide.html#transfferingrecord.

IV. Cross References/Related Policies

Intellectual Property and Technology Transfer
Classification and Handling of Information

Privacy and Security
Record Retention and Disposal
CFR 200.333 Retention Requirements for Records
Research Compliance Program Manual

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