

# Data Access Procedure

June 2021

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**TARGet Kids! Methods Centre**  
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# 1. TARGet Kids!

## Overview

TARGet Kids! ([www.targetkids.ca](http://www.targetkids.ca)) is a network of children's doctors, researchers and families that aims to learn more about children's growth, development and health. The overall goal of the network is to prevent common health problems that begin at a young age by learning about factors that affect growth and development like nutrition, physical activity and the environment.

Since 2008, thousands of children and their families have participated in TARGet Kids! and have had an opportunity to learn about their child's health and find different ways to keep them healthy. TARGet Kids! continues to expand our network to include paediatricians and family physicians from diverse communities across Canada so that we can collect information that represent a variety of cultures and ethnicities.

TARGet Kids! recruits children who are under 6 years of age and are generally considered healthy. During the child's doctor's visit, we ask parents to complete questionnaires and we record the child's growth information. We collect a small blood sample to assess nutritional status and parents' height, weight and waist measurements are also taken. Data are collected at each available visit (up to 4 times during the first 2 years of life, then every year thereafter).

Project management occurs within the TARGet Kids! Methods Centre, located at SickKids, Peter Gilgan Centre for Research and Learning. Blood samples are processed by Mount Sinai Services and data are managed at the Applied Health Research Centre (AHRC) of St. Michael's Hospital.

## Goals

1. To build a state of the art child cohort through a primary care practice-based research network
2. To learn about children's health and well-being as they grow and develop
3. To test promising preventative interventions to raise healthy children
4. To maximize the value of children's data through linkage across sectors
5. To implement new knowledge to help all children reach their full potential

# 2. Data Access Procedure

## Purpose

Scientific data and knowledge are common goods and should be shared within an appropriate framework. The principles of data access and sharing enable high-quality scientific research. The TARGet Kids! Data Access Procedure has been developed in order to enable informed and efficient collaboration and ensure that data are being used in a scientific and ethical manner.

## Scope

- a. This document is intended for external Applicants wishing to access TARGet Kids! data. Members of the TARGet Kids! Science Review Committee and their trainees are encouraged to use the Data Access Framework as outlined in the Science Review Committee Terms of Reference.
- b. This document details the procedures and requirements for accessing TARGet Kids! data. These data include, but are not limited to, data from self-administered questionnaires, physical measures, socio-demographic data and environmental data, biological samples and their derivatives.
- c. The data may not be used to address any questions other than the one(s) approved.

- d. Approval for any prospective data collection must be obtained by the TARGet Kids! Science Review Committee *before* funding is sought.
- e. Access to TARGet Kids! data is granted for the period agreed upon in the *Data Access Memorandum of Understanding (MOU)*. Applicants can ask for renewal.
- f. This document will protect the privacy of TARGet Kids! participants and their families and the confidentiality of their data.

This document will be reviewed every two years.

## Access to Samples

TARGet Kids! biological samples constitute a finite resource. The procedures to ensure that this resource is optimally used, according to the long-term research goals of TARGet Kids! are not currently covered by this document. Procedures concerning access to samples will be made available to researchers at a later date.

## 3. Definitions

**Term:** Aggregate Data

**Definition:** Summed and/or categorized de-identified data that have been analyzed and placed in a format that precludes further analysis (e.g., in tables or graphs). Aggregate data do not include protected health information.

**Term:** Ancillary Study

**Definition:** An investigation that involves the collection and analysis of additional data and/or samples from research participants.

**Term:** Applicant

**Definition:** A Canadian or international researcher conducting research relevant to TARGet Kids! and who is applying for access to TARGet Kids! data. All applicants must be affiliated with an institution.

**Term:** Approved User

**Definition:** An Applicant granted access to TARGet Kids! data by the Science Review Committee. Access is provided for the period of time agreed upon in the *Data Access MOU*.

**Term:** Dataset Creation Plan (DCP)

**Definition:** A plan outlining the variables required for proposed analysis of TARGet Kids! data.

**Term:** De-identified Data

**Definition:** Data for which identifiers have been removed.

**Term:** Derived Data

**Definition:** Any and all data generated from or based upon the use of TARGet Kids! data and/or TARGet Kids! biospecimens for scientific analyses.

**Term:** Research Participants

**Definition:** Individuals who have contributed data to TARGet Kids!

**Term:** TARGet Kids! Executive Committee

**Definition:** A committee comprising the TARGet Kids! Co-Principal Investigators and TK management team (Epidemiologists, Project Manager(s), Project Coordinator(s) and Biostatistician) that will review and approve/deny access applications and provide overall oversight.

**Term:** TARGet Kids! Operations Team

A team comprising of the Project Manager, TK Project Coordinators, and Clinical Research Specialist (AHRC) who oversees the general operations and procedures of TARGet Kids! and its ancillary studies.

**Term:** TARGet Kids! Investigator

A researcher who collaborates with TARGetKids! to conduct research.

## 4. Safeguards for the protection of PHI

All data transfers will be done securely. Approved Users will be assigned a password when the dataset is provided.

Approved Users accessing TARGet Kids! data will respect the privacy of participants and the confidentiality of their data at all times. All reasonable efforts to maintain the security and confidentiality of the accessed data, including those outlined below, should be employed. The Approved User must not attempt to re-identify any individual TARGet Kids! participants by any means. If a participant is involuntarily identified, the TARGet Kids! Methods Centre must be immediately informed in writing and this information must be destroyed and neither recorded nor disclosed. The postal code variable is an indirect identifier and any data access request that includes postal code will be subject to thorough review to determine if the variable is needed.

- a. Administrative safeguards: Subjects coded, computer passwords ONLY with research team, locked folder on shared drive, designated individual responsible for controlling who has access to the data.
- b. Physical safeguards: Locked office, locked storage unit, access cards, cipher/coded locks, biometric authentication.
- c. Technical safeguards: Files/folders password protected, computer password protected, firewalls, network drive, encrypted laptop, encrypted USB key.

*The SickKids and Unity Health Toronto Policy requires that PHI be stored with two separate Passwords/Authentication methods.*

## 5. Data Access Documents and Procedures

- a. Data Access Application Form  
Applicants wishing to obtain TARGet Kids! data complete the Data Access Application Form. This application will be sent to the TARGet Kids! Executive Committee for review and evaluation.
- b. Data Access Memorandum of Understanding (MOU)  
Approved Users will be required to sign and comply with the Data Access MOU.
- c. Final Project Report  
Once an approved research project has ended, Approved Users must submit a Final Project Report to the TARGet Kids! Executive Review Committee. This Report requires a summary of the research findings and publications.

The procedure to obtain access to TARGet Kids! data is outlined in figure 1:

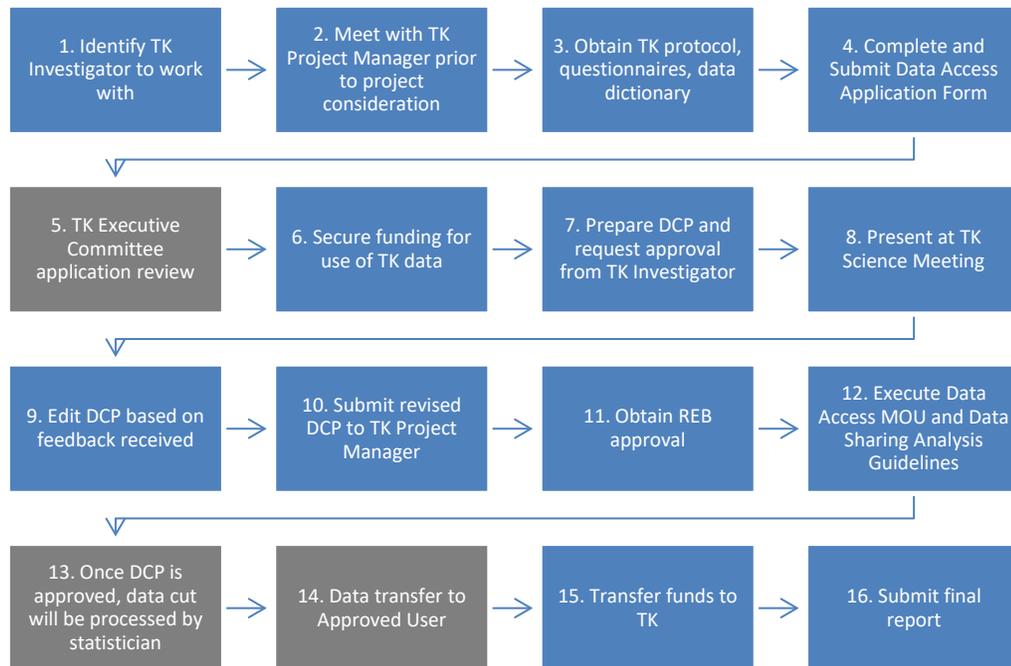


Figure 1 - TARGet Kids! Data Access Procedure

## 6. Review of Applications

### a. General Procedure

A Data Access application should only be submitted after meeting with the TK Project Coordinator has occurred. A letter of support from the TARGet Kids! Executive Committee may be requested for funding applications and ethics submissions.

The TARGet Kids! Executive Committee will review the Data Access Application Form and associated documentation during the next scheduled meeting. Unapproved applications will be returned to the applicant, accompanied by the rationale and list of reasons for the return. Resubmissions will be permitted. In the case of an approval, a member of the Executive Committee will notify the Applicant of the approval, provide an approval number and forward the DCP information to the now Approved User to prepare. The Approved User will be required to sign the Data Access MOU and Data Analysis Sharing Guidelines. Once the MOU has been executed, data will be provided to the Approved User for a period of one year.

### b. Ancillary Studies Requiring Participant Contact

Many TARGet Kids! Research Participants have consented to be approached for future studies. Applicants may submit a Data Access Application Form for future studies that require the collection of additional information through questionnaires, physical measures, or environmental or biological samples. The TARGet Kids! Operations Committee will identify overlapping initiatives in proposed studies and may offer suggestions for combining substantially similar proposals. Once the required funding is received, the Applicant should then apply to their local REB in parallel to submitting the Data Access Application Form. An ethics approval letter, once received, must be forwarded to the TARGet Kids! Methods Centre to complete the application. Summaries of approved and non-approved projects will be forwarded to the TARGet Kids! Advisory Committee annually.

Applicants proposing ancillary studies that require additional participant involvement will provide TARGet Kids! with all data collection instruments (e.g., questionnaire, chart review form) and/or a description of the additional measurements or samples that will be collected, and informed consent

documents developed for the ancillary study. The consent form for the ancillary study must clearly stipulate that it is ancillary to TARGet Kids! and participation in the ancillary study is not required for continued participation in TARGet Kids! Investigators will be required to submit data collected to TARGet Kids! once data collection is complete. This will allow future investigators access to enriched data to enable them to build upon previous research.

c. Requests for Linked Data

Additional fees apply for applications requesting linkage to external data (e.g., up to \$10,000 for IC\ES).

d. Criteria for Review

All Data Access Application Forms will be assessed by the TARGet Kids! Executive Committee, which will consider, among other relevant items, the following:

- Whether there is a written scientifically and ethically appropriate research plan with sufficient detail for review;
- If the Applicant is qualified to carry out the proposed research;
- The adequacy of the Applicants' and the Host Institutions' processes regarding privacy and confidentiality;
- Compatibility of the research study with the objectives of TARGet Kids!; and
- Whether the Applicant has adequate financial and human resources to effectively complete the study (collaborators and staff).

## 7. Posting Derived Data

TARGet Kids! recognizes the scientific importance of improving the depth and breadth of its Registry database. In order to achieve this goal, Approved Users accessing TARGet Kids! data are required to submit Derived Data to TARGet Kids! once analysis is complete and/or manuscript has been submitted for publication.

## 8. Publication Policy

Approved Users of TARGet Kids! data are strongly encouraged to publish their research results so as to benefit both the scientific community and the general population.

The TARGet Kids! co-Principal Investigators will be listed as authors of any applicable publication. Authors must acknowledge the contribution of TARGet Kids! in their publications or presentation where data from TARGet Kids! were used. All publications and presentations must contain the following:

*“The data used for this research were made available by the TARGet Kids! Collaboration. We wish to thank the participants and site investigators who make up the TARGet Kids! network”.*

Information on data sharing may be requested for publication. An example to include in the final manuscript is below:

Data are available upon request by contacting [www.targetkids.ca/contact-us/](http://www.targetkids.ca/contact-us/). The full data are not freely available to respect the confidentiality of our participants, ensure data integrity, and avoid scientific overlap between projects. Once initial contact has been made, we request a short research proposal which will be subject to review by the TARGet Kids! Executive Committee and approval by institutional IRBs.

Upon publication, a copy of the publication must be sent to the TARGet Kids! Methods Centre for inclusion on the TARGet Kids! website.

## The Media

All press releases on research arising from the study must be shared with the TARGet Kids! Methods Centre. We may ask authors to prepare a précis of important papers and/or lay summaries to include in reports to funders and future applications for future core funding.

## 9. Intellectual Property Policy

Approved Users and their host institution agree not to make intellectual property claims on TARGet Kids! primary data, but may choose to obtain intellectual property rights on subsequent innovations and downstream discoveries arising from such data.

## 10. Destruction of Data

After the approved research project is completed and the results are submitted for publication, the Approved User will be permitted to archive the transferred data for a period of time required for peer review, and for audit purposes for a maximum of 5 years. Alternatively, an Approved User may destroy the transferred data immediately or after a period of time with the agreement of TARGet Kids!. Once this period of time has elapsed, the Approved User must undertake to destroy all the data as well as all copies of the data. The Approved User shall submit a letter to confirm the destruction of the data to the TARGet Kids! Methods Centre.

## 11. Financial Conditions

The Approved User shall reimburse TARGet Kids! for any reasonable costs that may be incurred when preparing and sending the data to the Approved User, or contacting Research Participants for ancillary studies. A cost-recovery budget example is specified in tables 1 and 2 below. The final amount will be determined by the TARGet Kids! Executive Committee. Invoices will be prepared once the dataset is provided or once recruitment begins for ancillary studies.

The data access fees are payable for the retrieval and preparation of the dataset per approved project, not for each project team member. Information to be included in grant proposals regarding TARGet Kids! data access fee can include the following:

*“For this study, the TARGet Kids! registry database will be accessed to provide baseline data as well as long term outcomes of the children enrolled in this study. As such, an annual registry fee is applied to support the technical fees and staffing costs associated with the TARGet Kids! registry; this includes, for example, server space, staffing costs associated with validating and extracting the data from the registry, and staffing costs to perform the necessary registry database changes required to support this study.”*

Access fees vary, based on the type of request and scale of the project.

1. Requests for data (e.g., retrospective study/secondary data analysis):  
The maximum fee for extraction of TARGet Kids! data is \$12,000 per project (for the first pull). See Table 1.

Principal Investigators currently (at the time of request) holding a grant which contributes to prospective data collection for TK will follow the discounted fee structure outlined in table 2.

Table 1: Fee structure for secondary data analysis

| Item                                                                                                                                                                                                                                           | Fee                                                    |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------|
| <b>Administrative Fee</b><br>Project Management Time (e.g. Project Manager, Project Coordinator, Statistician, Research Specialist)                                                                                                            | \$2000 (Flat fee)                                      |
| <b>Extraction costs</b><br>Statistician – review of file, identifying relevant variables, programming/coding, data extraction, preparation of data set (e.g. merging data from various sources), sending data securely, and project management | \$10,000 or \$20/participant (to a maximum of \$8,000) |
| <b>Subtotal:</b>                                                                                                                                                                                                                               | \$12,000                                               |
| <b>Additional TK Fees:</b>                                                                                                                                                                                                                     |                                                        |
| <b>Linked data (e.g. ICES, BORN, EDI)<sup>1</sup></b><br>Requests for data collected outside of the TK data dictionary (note, this is in addition to fees charged by ICES or other agencies)                                                   | \$3000 (flat fee)                                      |
| <b>Amendment fee</b><br>Additional request for data/variables in the TK data dictionary >12 months after initial data cut.                                                                                                                     | \$750 per interval                                     |

<sup>1</sup> Note: Additional fees may apply to researchers seeing to access linked data from ICES, BORN, or EDI that was previously procured by TARGet Kids! registry. For example, ICES fees may include (1) ICES Data Privacy, Security and Access (DPSA) fee, (2) ICES Data Analyst, (3) ICES Data & Analytic Virtual Environment (IDAVE) Access and User fees.

Table 2: Fee structure, secondary data analysis for Principal Investigators currently holding a grant

| Item                                                                                                                                                                                                                                           | Fee                                                   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|
| <b>Administrative Fee</b><br>Project Management Time (e.g. Project Manager, Project Coordinator, Statistician, Research Specialist)                                                                                                            | <i>Waived</i>                                         |
| <b>Extraction costs</b><br>Statistician – review of file, identifying relevant variables, programming/coding, data extraction, preparation of data set (e.g. merging data from various sources), sending data securely, and project management | \$5,000 or \$15/participant (to a maximum of \$5,000) |
| <b>Subtotal:</b>                                                                                                                                                                                                                               | \$5,000                                               |
| <b>Additional TK Fees:</b>                                                                                                                                                                                                                     |                                                       |
| <b>Linked data (e.g. ICES, BORN, EDI)<sup>2</sup></b><br>Requests for data collected outside of the TK data dictionary (note, this is in addition to fees charged by ICES or other agencies)                                                   | \$3000 (flat fee)                                     |
| <b>Amendment fee</b><br>Additional request for data/variables in the TK data dictionary >12 months after initial data cut.                                                                                                                     | \$750 per interval                                    |

2. Request for additional data or biomaterial collection.  
Approved Users will be expected to meet costs of collection of new data. Funding obtained for contacting the cohort, recruitment, data collection and the conduct of the proposed study will be transferred to TARGet Kids! to enable pooling of resources to contribute to the maintenance of the network.

Contact the TARGetKids! Project Manager for Budget Development and Study Start-up Checklist information.

## 12. References

- a. Canadian Partnership Against Cancer – Canadian Partnership for Tomorrow Project Data Access Policy March 2015
- b. Ontario Health Study Data Access Policy May 27, 2011
- c. ALSPAC Access Policy v 7.0 September 2016

<sup>2</sup> Note: Additional fees may apply to researchers seeing to access linked data from ICES, BORN, or EDI that was previously procured by TARGet Kids! registry. For example, ICES fees may include (1) ICES Data Privacy, Security and Access (DPSA) fee, (2) ICES Data Analyst, (3) ICES Data & Analytic Virtual Environment (IDAVE) Access and User fees.



# Appendix 1: TARGet Kids! Data Access Application Form

Date: \_\_\_\_\_  
MM/DD/YYYY

**Section 1: Research Personnel**

Applicants:

*The names, institutions and lay summaries of the scientific abstracts of all applicants having been granted access to TARGet Kids! data will be added to its publicly accessible access registry on the TARGet Kids! website.*

| <b>a) Principal Applicant</b> |  |
|-------------------------------|--|
| Name:                         |  |
| Institution:                  |  |
| Position:                     |  |
| Email:                        |  |
| Telephone:                    |  |
| Address:                      |  |

Please submit the CV of the Principal Applicant with the application.

| <b>b) Co-applicant:</b> |  |
|-------------------------|--|
| Name:                   |  |
| Email:                  |  |
|                         |  |
| Name:                   |  |
| Email:                  |  |
|                         |  |

Please insert additional rows if there is more than one co-applicant.

Is the data being requested for a student thesis or project? Yes  No

| <b>c) Research Team</b>                                                                                                                                                                                                                                                                                                   |             |          |                                       |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|----------|---------------------------------------|
| Excluding those investigators listed above, please provide the names of all investigators, collaborators, students and research staff that will have access to the data in order to work on the research project. A valid institutional email address for each name along with their job title/function is also required. |             |          |                                       |
| Name                                                                                                                                                                                                                                                                                                                      | Affiliation | Position | Contact Information (email/telephone) |
|                                                                                                                                                                                                                                                                                                                           |             |          |                                       |
|                                                                                                                                                                                                                                                                                                                           |             |          |                                       |
|                                                                                                                                                                                                                                                                                                                           |             |          |                                       |

## Section 2: Research Project

a) Project Title:

b) Scientific Abstract:

Please provide a clear scientific description of the research project and its specific hypotheses in no more than 500 words.

c) Lay Summary of Project:

Please provide a short description of the project for the general public in no more than 250 words. Scientific jargon and acronyms should be avoided as much as possible. For approved projects, this description will be made available on the TARGeT Kids! website.

d) Ethics Approval:

Has this study been approved by a research ethics board? Yes  No

If yes, please append a copy of the approval.

If no, please specify arrangements for obtaining the appropriate approvals:

*TARGeT Kids! is not responsible for the ethics approval/monitoring of individual research projects and bear no responsibility for the Applicant's failure to comply with local/national ethical requirements.*

d) Funding:

Has the project been or will it be peer reviewed? Yes  No

If yes, by what organization?

Has funding been approved? Yes  No  Not applicable

Funding source (please attach a detailed budget for this project). If “Not applicable” was selected, please explain why funding is not required:

e) Proposed Methods and Analysis:

Are you requesting aggregate data or individual-level data?  Aggregate Data  Individual-level Data

Please list the variable domains that you are requesting for this project. A copy of the TARGet Kids! data dictionary is available here (*INSERT LINK*):

f) Please describe the design and methodology of the proposed project, including the primary outcome measures and the methods that will be used to analyze the study data. If the proposed project involves contacting TARGet Kids! participants for additional data collection, please attach a copy of the proposed consent form and the data collection form or instruments.

g) Data Linkage:

Will data from other sources be utilized to complete the proposed project? Please list all data linkages.

h) Proposed Timelines:

Briefly outline the proposed timelines required to complete the project, including the projected start date, the number of months required to complete the project, and the expected date data will be returned to TARGet Kids! or destroyed.

i) Return of Study File:

Outline how the study file, including any new data or samples collected as part of the proposed project will be returned to TARGet Kids!

### Section 3: Data Security

a) My institution has a formal IT security policy: Yes  No

b) Safeguards:

Describe the safeguards in place, both physical and electronic, to protect the privacy and security of TARGet Kids! data. If TARGet Kids! data will be stored on a shared computer or network accessible computer, please describe how access will be limited to those individuals named in the access request.

Describe your plan to control and monitor which individuals will have access to TARGet Kids! data and how you will familiarize them with the restrictions on its use.

Describe your plan to archive or destroy TARGet Kids! data after the Data Access Memorandum of Understanding expires.

---

Principal Applicant:

Name: \_\_\_\_\_

Title and position: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

---

**Please email a PDF of the signed Data Access Application Form to [targetkids.study@sickkids.ca](mailto:targetkids.study@sickkids.ca)**

**Next step:** Complete the *Dataset Creation Plan*

---

**TARGet Kids! Methods Centre Use Only**

Date application received: \_\_\_\_\_

File number: \_\_\_\_\_

Date application reviewed: \_\_\_\_\_

Initial consultation date: \_\_\_\_\_

Science Meeting presentation date: \_\_\_\_\_



## Appendix 2: TARGet Kids! Data Access Memorandum of Understanding

This Memorandum of Understanding (MOU) provides the terms of access to the data generated by TARGet Kids!. In signing this MOU, you agree to be bound by the terms and conditions of access set out therein.

For the sake of clarity, the terms and conditions of access set out in this MOU apply to the Approved User. Approved User is referred in this MOU as “You” and “Your”, and shall be construed accordingly.

### DEFINITIONS

**TARGet Kids!:** a network of children’s doctors, researchers and families that aims to learn more about children’s growth, development and health.

**TARGet Kids! Data:** data associated with unique, but not directly identifiable TARGet Kids! participants.

**Research Participants:** individuals who have contributed their data to TARGet Kids!

**Approved User:** applicant who was granted access to TARGet Kids! data.

### TERMS AND CONDITIONS

Project title: \_\_\_\_\_

In signing this MOU:

1. You agree to use TARGet Kids! data in compliance with the TARGet Kids! Data Access Procedure, included as Appendix 1 of this Data Access MOU, and which is an integral part of the latter.
2. You agree to use TARGet Kids! data for the approved purpose and research project described in the Data Access Application Form and as approved by your ethics committee. Use of the data for a new purpose or project will require a new application and approval.
3. You agree to preserve, at all times, the confidentiality of the information and TARGet Kids! data. In particular, you undertake not to use, or attempt to use TARGet Kids! data to compromise or otherwise infringe the confidentiality of information on Research Participants and their right to privacy.
4. You agree in case of involuntary identification of a participant, this information should be destroyed and you undertake not to record or disclose that participant’s identity to anyone and not to try to contact that participant.
5. You agree to protect the confidentiality of research participants in any research papers or publications that you prepare by taking all reasonable care to limit the possibility of identification.
6. You agree not to link or combine TARGet Kids! data provided under this MOU to other information that could re-identify the research participants, even if access to that data has been formally granted to you, or is freely available without restriction.
7. You agree not to transfer or disclose TARGet Kids! data, in whole or in part, or any identifiable material derived from TARGet Kids! data, to anyone not listed in the Data Access Application Form, except as required for data safety monitoring, audits or program management. Should you wish to share TARGet Kids! data with an External Collaborator, this third party must complete a separate Data Access Application Form and follow the normal access procedures.
8. You accept that TARGet Kids!:
  - a. bears no legal responsibility for the accuracy or comprehensiveness of the TARGet Kids! data; and

- b. accept no liability for indirect, consequential, or incidental, damages or losses arising from use of TARGet Kids! data, or the unavailability of, or break in the access to TARGet Kids! data for whatever reason.
- 9. You shall reimburse TARGet Kids! for any reasonable costs that may be incurred when preparing and sending the data to you.
- 10. You agree to recognize the contribution of TARGet Kids!, including a proper acknowledgement in all reports, presentations and publications resulting from your use of the TARGet Kids! data.
- 11. You recognize that nothing in this MOU shall operate to transfer to you any intellectual property rights on TARGet Kids! primary data. However, you have the right to develop intellectual property rights on subsequent innovations and downstream discoveries arising from such data. In doing so, you agree to implement licensing policies that will not obstruct further research and follow the U.S. National Institutes of Health's *Best Practices for the Licensing of Genomic Inventions* and the *OECD Guidelines for the Licensing of the Genetic Inventions*.
- 12. You will use all reasonable endeavours to ensure that the data – including copies and backup copies – in your possession or under your control shall be destroyed, unless obligated to retain the TARGet Kids! data for archival purposes in conformity with audits or legal requirements, upon a) the reasonable request of TARGet Kids!; b) the expiration of this MOU; or c) in the event that you are in breach of any of the conditions of this MOU. Data archived for audit or legal requirements may be retained for a maximum of 5 years. When requested by TARGet Kids!, you shall certify that the transferred data and all copies thereof were destroyed.
- 13. You must report to TARGet Kids! any significant changes to your research project and whether such change influences ethical approval.
- 14. You accept that it may be necessary for TARGet Kids! or its appointed agent to alter the terms of this MOU from time to time in order to address new concerns. In this event, TARGet Kids! or its appointed agent will contact you to inform you of any changes.
- 15. You agree to return data and results that arose from the accessed data back to TARGet Kids! at the end of your project.
- 16. You agree to submit a Final Project Report on completion of the agreed purpose.
- 17. You agree to distribute a copy of this MOU and explain its content to any research member mentioned in the Data Access Application Form.
- 18. TARGet Kids! reserves the right to use legal action against you for any damages caused by breach of this MOU.
- 19. This MOU shall be construed, interpreted and governed by the laws of Canada and the province of Ontario.

I have read and agree to abide by the terms and conditions outlined in the Data Access Memorandum of Understanding. Yes  No

**Principal Applicant:**

Name: \_\_\_\_\_ Title and position: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**TARGet Kids! Executive Committee Chair/Representative:**

Name: \_\_\_\_\_ Approval Number: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Please email a PDF of the signed Data Access MOU to [targetkids.study@sickkids.ca](mailto:targetkids.study@sickkids.ca)

## Appendix 3: TARGet Kids! Data Sharing and Analysis Guidelines

1. All TARGet Kids! data files should be located only on SMH or SickKids issued computers or password protected encrypted USB keys. **TARGet Kids data should not be located on personal laptops, dropbox, email or any other unencrypted devices.**
2. “Data” includes any files that contain individual level (person-specific) TARGet Kids questionnaire or clinical/lab information (e.g., .sas7dbat, .csv, .Rdata or .xls). Even if your data does not contain any personal identifiers we would like to keep it secure and it should only be saved on approved devices.
3. Analysis should be run directly from the encrypted location. For example, SAS libnames and R directories should point to the encrypted USB device. R workspaces should be saved only on encrypted devices.
4. **All data requests should go through the team biostatistician (David Dai) and data should only be distributed by him.** Data will be distributed through secure encrypted SMH data transfer or directly on an encrypted USB key. All data distributed through secure email data transfers needs to be moved to either an encrypted USB key or SickKids/SMH computer – not to personal laptops.
5. **Do not share or distribute data with anyone** (even within the team) and **data files should never be sent by email.** It is important for the team to keep track of who has access to which variables and this can only be done by ensuring all data requests are facilitated by the team biostatistician.
6. Upon completion of a project, all datasets, statistical programs and encrypted USB keys should be returned.
7. **Statistical programs, including sas code (editor files “.sas”) or R syntax (R files “.R”), should be backed up regularly in a separate location. Since the program files do not contain any individual level data they should be regularly backed up in a secondary location (e.g., personal laptop drive or dropbox OR One Drive are all acceptable).** These programs should contain all the statistical code necessary to recreate your datasets, derive any variables and conduct your analysis (see data analysis guidelines below).
8. Please report any lost data files to your TK supervisor. The reason for keeping data on encrypted devices is to ensure that any lost data cannot be accessed by others. Datasets can always be re-created if your programs are backed up in a second location.
9. **Please do not hesitate to ask if you have any questions or concerns.** It is understood that for many trainees this will be their first data analysis project and as part of the learning experience we encourage you to build good data handling and management techniques.
10. Familiarize yourself with the SickKids and SMH privacy policies on the intranet and PHIPA.

Reviewed by: \_\_\_\_\_ Date: \_\_\_\_\_

## Data Analysis Guidelines

It is good practice to always clearly label your data analysis files and annotate your programs with comments. You should be able to go back to your programs a year later and remember what was done and why. Anyone else should be able to go back through your files and easily understand what was done.

1. Two folders should be created on your password-protected encrypted USB key under a project subheading that could be easily found by anyone else looking at your data.
  - a. Data
  - b. Statistical Program Files (note, these should also be backed up in a secondary location)
2. The Data folder should contain your permanent datasets. Ideally this will only include a few datasets – your source datasets and a final dataset. Although it is expected that you will generate many temp datasets in your data cleaning. The temporary datasets should be deleted at the end of each session. Datasets should be **named with the project name and date**. For example:
  - a. bmi\_iron\_data\_31May2017.sas7bdat
  - b. bmi\_iron\_final\_31May2017.sas7bdat
  - c. An “Archive” subfolder can be created with any other datasets that you need to keep. Keeping in mind it is hugely confusing if you save a large number of datasets. Aim for one final dataset.
3. The Statistical Program Files folder should contain all clearly labelled programs used for the final analysis. These should be self-explanatory and another analyst should be able to re-run in the correct order to recreate your final analysis. For example:
  - a. 01\_datacleaning\_01Jun2017.sas (or .txt)
  - b. 02\_variable\_creation\_02Jun2017.sas
  - c. 03\_regression\_analysis\_05Jun2017.sas
  - d. 04\_sensitivity\_analysis\_06Jun2017.sas
  - e. 05\_manuscript\_revisions\_14Aug2017.sas
  - f. “Archive” subfolder with old versions of code or other things you tried that did not make it into final analysis
4. All Program Files should include detailed comments throughout clearly defining what was done and why. Although it may seem tedious at the time of analysis, this will pay off immensely in the long run.
5. Each Program Files should be clearly labeled with a project header. For example:

```
* Project Title:  Body Mass Index and iron stores in early childhood;
* Program name:   01_datacleaning_01Jun2017.sas   ;
* Investigators:  Patricia Parkin and Cory Borkhoff;
* Data created:  31May2017;
* Purpose:       Cleaning the ZBMI and iron status variables;
*****;
*data location:  E:\TargetKids\BMI_iron\Data analysis (encrypted USB key)
*Input datasets: iron.bmi_iron_data_31May2017 (from David);
*output dataset: iron.bmi_iron_final_31May2017
*****;
```

## Appendix 3: Data Cut

Once your Dataset Creation Plan (DCP) has been approved, you are requested to indicate which variables you require from the TARGeT Kids! data dictionary and where the variables come from (e.g., COVID study, NHQ, NutriStep, etc.) using the table below.

Please contact the TARGeT Kids! biostatistician, Charlie Keown-Stoneman, PhD ([Charlie.keown-stoneman@unityhealth.to](mailto:Charlie.keown-stoneman@unityhealth.to)), for access to the TARGeT Kids! data dictionary.

| Research Question                        | Database            | Variable Name (Optional) |
|------------------------------------------|---------------------|--------------------------|
| e.g. Parent important of vaccine on self | e.g. COVID-19 Study | e.g. nhq_vaccine_import  |
|                                          |                     |                          |
|                                          |                     |                          |
|                                          |                     |                          |