CPRI Research Agreement:

Application for Disclosure of Information for Research Purposes

**This Research Agreement must be completed, signed and submitted (along with accompanying materials identified below) to Laura Theall, Research Coordinator via email at: laura.theall-honey****@ontario.ca****.**

It is essential that the documentation you provide be accurate, complete, and up to date; upon approval of your request, you will be bound to their terms via their inclusion in a confidentiality agreement. See Submission Guidelines at www.cpri.ca.

At the time of submission, the following materials must also accompany this form:

* *A copy of a full university Research Ethics Board application including specific details about methodology*
* *A copy of the university Research Ethics Board approval*
* *Certificate of completion of Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS) tutorial for ALL investigators; tutorial located at* [*www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/*](http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/)
* *Section I signed by ALL investigators*
* All related project materials including consent forms and data collection instruments
* NOTE: Applications by CPRI staff may not require all materials listed above, depending on the research activity proposed. Please contact a CPRI Research Coordinator to confirm submission requirements.

CPRI is strongly committed to supporting research and encourages the use of its research data for this purpose. Our goal is to make timely and accurate research data available to researchers, while respecting our privacy obligations under the Personal Health Information Protection Act, 2004 (PHIPA).

Sections to be completed (use checklist at the end of this document to ensure application is complete)

* Requestor
* Research Project
* Statement by Researcher
* Safeguards
* Research Data Linkages
* Timeframe, Research Data Retention/Destruction, Return
* Benefits, Harm, and Conflict of Interest
* Project Impacts on CPRI and Clients
* Acknowledgements by Appropriate Authorities

Completed requests will be signed and authorized by either the CPRI Director or the CPRI Research Review Committee. Final decision for all research conducted at CPRI rests with the CPRI Director or the CPRI Research Review Committee. CPRI may approve a request, deny a request or request further information or clarification before reaching a decision.

The CPRI Research Review Committee meets every month from January to November (no meeting is held in December). Full submissions must be received by 5 pm on the 1st day of the month before the next meeting to be included on the agenda. However, each meeting is limited to review 5 submissions. Submissions will be reviewed on a first-come first-served basis. The Committee Coordinator will confirm receipt of the submission and the meeting date within 2 working days of receipt. A response from the Committee will be emailed to the applicant within 2 weeks after the meeting.

# Section A. Requestor

Complete one (1) of the following

## REQUEST FROM AN ORGANIZATION:

|  |  |
| --- | --- |
| Name of the organization requesting the research data:      | Name of the contact person:      |
| Address:      | Role/Title:       |
| Phone:       |
| Fax:       |
| Email:       |

## REQUEST FROM AN INDIVIDUAL:

|  |  |
| --- | --- |
| Name:      | Name of the organization affiliated with:      |
| Address:      | Role/Title:            |
| Phone:       |
| Fax:       |
| Email:       |

# Section B. Research Project

1. **TITLE OF RESEARCH PROJECT**:

1. Append a full written proposal describing the research project. The proposal should include the objectives and methodology of the research and the anticipated public and/or scientific benefit as well as a description of the CPRI research data elements that are requested, and how this research data will be used, including publications.

NOTE: Record level requests for research data are normally regarded as a request for Personal Health Information. The written proposal shall provide an explanation as to why consent to the disclosure of PHI is not being sought from the individuals to whom the PHI relates. If PHI is to be linked to other research data, the written proposal should include an explanation of why such linkage is necessary.

1. **IDENTIFY THE SPONSORING OR FUNDING ORGANIZATION FOR THIS RESEARCH PROJECT:**

1. **FUNDING GRANT INFORMATION** (if applicable):

Period of Grant: from       to       Amount of Grant:

1. **ETHICS APPROVAL STATUS:**

Identify all Research Ethics Boards (REBs), the status of the applications and provide a copy of any decision.

|  |  |
| --- | --- |
| Research Ethics Board:      | Current Status:      |
| Research Ethics Board:      | Current Status:      |
| Research Ethics Board: | Current Status: |
| Research Ethics Board:      | Current Status: |

1. **PRINICPAL INVESTIGATOR AND CO-INVESTIGATORS:**

|  |  |
| --- | --- |
| Principal Investigator’s Name & Title:      | Name of the organization affiliated with:      |
| Address:      | Qualifications:       |
| Email:       |
| Phone:       | Fax:       |

### Optional

|  |  |
| --- | --- |
| Co-Investigator’s Name & Title:      | Name of the organization affiliated with:      |
| Address:      | Qualifications:       |
| Email:       |
| Phone:       | Fax:       |

### Optional

|  |  |
| --- | --- |
| Co-Investigator’s Name & Title:      | Name of the organization affiliated with:      |
| Address:      | Qualifications:       |
| Email:       |
| Phone:       | Fax:       |

**Recopy this chart as necessary to add additional Co-investigators**

# Section C. Statement by Researcher

The Researcher is seeking to have access to PHI at CPRI. In adherence with privacy obligations under the Personal Health Information Protection Act, 2004 (PHIPA), CPRI provides the minimum amount of research data reasonably necessary to complete desired research activities (PHIPA, 2004, c. 3, Sched. A, s. 49 (2).

Provide a detailed list of all research data elements (e.g., items, sections of an instrument, specific scales) required and justify the need for the research data element (i.e., explain how access to this research data element contributes to your analysis or helps you address your research question). See Appendix B for an example. You may fill in the following table for requests involving a small number of elements. For more extensive requests, please attach a list of research data elements requested in a separate document.

Please note, this information is required for approval. Submission of an application with insufficient information about requested research data elements will delay approval as the Committee will request more information.

|  |  |
| --- | --- |
| C1. Research Data Element/Requested | Description (required) |
|       |       |
|       |       |
|       |       |
|       |       |
|       |       |

**C2. Please describe your desired sample (size, stratification, inclusion/exclusion criteria)**

The Researcher understands that these records may contain confidential information about individual clients and other identifiers such as names of physicians, clinics and programs that may otherwise be in a form where individual patients may be identifiable.

If access to these records is granted, the Researcher understands and will abide by the provisions of the **CPRI** **Non-Disclosure/Confidentiality Agreement for Researchers** as well as the following terms and conditions:

* The information obtained from CPRI will be used only for the research purposes outlined in this Research Agreement.
* In addition to the Investigator and Co-investigators mentioned above, the following persons (listed below) may have access to the records for the research purposes described in the appended research project proposal. Their name, role in the research project, relevant qualifications and reason why they need access to records in a form in which individuals to whom the records pertain may be identifiable, must be described below.
* The Researcher will be responsible for having each of these persons sign the **CPRI** **Non-Disclosure/Confidentiality Agreement for Researchers** and returning it to CPRI before access is given to any research data. No other person shall have access to the records in a form where individuals may be identifiable.

**C3. Person/s who may have access to requested research data (in addition to the Investigator and Co-Investigators already listed above):**

|  |  |
| --- | --- |
| Name of the person who may have access to the records:      | Name of the organization affiliated with:      |
| The person’s role in the research:      | Why is access required for this person?      |
| Address:      | Qualifications for access to this research data:      |
| Email:       |
| Phone:       | Fax:       |

|  |  |
| --- | --- |
| Name of the person who may have access to the records:      | Name of the organization affiliated with:      |
| The person’s role in the research:      | Why is access required for this person?      |
| Address:      | Qualifications for access to this research data:      |
| Email:       |
| Phone:       | Fax:       |

**Recopy this page as necessary to add additional persons who will require access to the research data.**

# Section D. Safeguards

Persons requesting and receiving research data from CPRI must demonstrate that appropriate administrative, physical and technical safeguards are in place to safeguard the research data from inappropriate use or disclosure.

Premises where records (both physical and electronic) will be kept have up to date physical security measures in place (e.g. door locks / access cards)?

[ ] Yes [ ]  No

All physical copies of records will be kept in a locked cabinet(s)? Keys to these cabinets must be restricted to people authorized for access to this research data.

[ ]  Yes [ ]  No

Passwords and encryption software are in place to protect files? Processes are in place to ensure access restricted to people authorized for access to this research data.

[ ]  Yes [ ]  No

Research data is anonymized using a unique study number (when collected or as soon as possible thereafter)?

[ ]  Yes [ ]  No

Describe any other measures in place to prevent unauthorized collection, use, and/or disclosure of research data. Include references to, and copies of, any third party assessments or assurances with respect to information security and privacy practices, where such are available.

# Section E. Research Data Linkages

Please complete if CPRI-provided research data is to be linked to other data.

|  |  |
| --- | --- |
| Research data to which linkage is planned | How will it be linked? |
|       |       |
|       |       |
|       |       |
|       |       |
|       |       |

Please include an explanation as to why the linkage of personal health information to other information is required, if the reasons are not included in your research proposal (section B. 2. above)

# Section F. Timeframe, Research Data Retention / Destruction, Return

1. When do you need the research data?

1. Study Timeframes:

 Project start date:

Project end date:

Time (months) needed to complete the project:

1. Date when access to research data from CPRI will no longer be required:

1. Date when research data received from CPRI will be returned or destroyed:

See Appendix C for confirmation form of research data and record destruction to be submitted once research has been approved and completed.

1. PHIPA and CPRI require that research data returned or destroyed must be done in a secure manner.
* Secure return of research data requires that the media containing the research data should be both encrypted (if electronic) and transported to the attention of the CPRI Research Department.
* Secure physical destruction of research data means destroying the media containing the research data (whether electronic media or paper) to a condition that prevents any reconstitution of the media (i.e. crosscut shredding).
1. Description of a) method of secure research data destruction/return and b) proof of secure destruction/return of all copies of the research data

## Section G. Benefits, Harm and Conflict of Interest

### Alternatives

Is it possible to perform the research without using Personal Health Information?

 [ ]  Yes [ ]  No

1. If No, explain why the research cannot be accomplished without the use of PHI (i.e. what alternative methods were considered)

1. Describe the levels at which results will be reported (e.g. level of individuals, institutions, geographic areas). Include the smallest reporting unit:

### Public Benefit

1. Identify the public benefit expected or anticipated from the research project:

1. Describe any way the use of personal health information in this research project might harm clients (e.g. identification, stigmatisation):

1. Describe how the Researcher intends to address the potential for harm:

### Possible Conflict of Interest

Do any of the researchers have conflict of interest to declare?

[ ]  Yes [ ]  No

If yes, specify:

## Section H. Project Impacts on CPRI Staff and Clients

1. Please identify resources that will be required from CPRI (e.g., staff time, space, equipment). See Submission Guidelines at www.cpri.ca for information about access to research data at CPRI and resources required.

1. Please outline the impact of the findings of this project on service at CPRI*.*

1. Please indicate the advantages and disadvantages of CPRI’s involvement with this project, specifically noting any difficulties that may be experienced.

1. Are there any potential burdens to clients and families at CPRI?

 [ ]  Yes [ ]  No

If yes, please explain.

## Section I. Acknowledgements by the Appropriate Authority at the Requestor Organization

* If and when this request is approved by CPRI, the Requestor and all those who will have access to the research data will sign the required **CPRI** **Non-disclosure/Confidentiality Agreement for Researchers** before the research data are provided by CPRI.
	+ In addition to the above, in the case where the Requestor or others who will have access to research data are students, the students’ principals or advisors are also required to sign the Non-disclosure/Confidentiality Agreement.
* The Requestor agrees to ensure that cell sizes less than 25 will not be reported without prior written approval from CPRI.
* The Requestor agrees that specific date ranges (e.g., months or years) will not be reported without prior written approval from CPRI.
* The Requestor agrees to ensure security and protection of record level research data as follows:
* The premises where records are kept will have up to date physical security measures in place, including locked cabinets for the physical records.
* Access to the computers and records stored in them will be restricted through use of passwords and other appropriate access control procedures.
* If records are photocopied, identifiers will be obliterated completely.
* Original personal health records received from CPRI will be either (i) securely returned to CPRI or (ii) securely destroyed, meaning all copies of such records will be shredded.
* Electronic media (e.g. magnetic and optic disks, CDs and cartridges) will be destroyed.

The Requestor, Principal Investigator and Co-Investigator(s) certify that the information reported in this form and the appended Research Project Proposal is accurate and agree to comply with the terms and conditions contained in this form.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Name |  | Signature |
|  |  |  |
| Title |  | Date |
|  |  |  |
| Name |  | Signature  |
|  |  |  |
| Title:  |  | Date:  |
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| Name |  | Signature  |
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| Title:  |  | Date:  |
|  |  |  |
| Name |  | Signature |
|  |  |  |
| Title |  | Date |
|  |  |  |

## Appendix A: Request Checklist

|  |  |
| --- | --- |
| All persons, both investigators and others, that may have access to the requested research data have been identified? | [ ]  Yes [ ]  No |
| Technical, Physical, and Administrative safeguards have been identified? | [ ]  Yes [ ]  No |
| Research Proposal is attached? | [ ]  Yes [ ]  No |
| All Research Ethics Boards are identified with the current status of their applications? | [ ]  Yes[ ]  No |
| TCPS certificate of completion attached for ALL investigators? | [ ]  Yes[ ]  No |
| Requested data elements are accurately identified? | [ ]  Yes[ ]  No |
| You are requesting the minimal amount of PHI necessary for your study and have justified the need for research data elements requested? | [ ]  Yes[ ]  No |
| If research data linkages are required, you have provided an explanation of their necessity? | [ ]  Yes [ ]  No |

**Appendix B: Sample Research Data Elements Request Table for Use in Section C1**

|  |  |
| --- | --- |
| Research Data Element Requested | Description (required) |
| Age | Required to conduct age-related analyses, related to hypothesis about how age impacts adverse effects |
| Gender | Required to conduct gender-based analyses, related to hypothesis about how gender impacts adverse effects |
| interRAI Child and Youth Mental Health (ChYMH) Severity of Self-harm scale | Required to address hypothesis about self-harm prevalence in population of study |
| interRAI ChYMH Sleep Disturbance Collaborative Action Plan  | Required to analyze impact of other variables studied on sleep |
| interRAI ChYMH items:B8, B9, B10 | Required to analyze impact of early involvement with child protective services |
| interRAI ChYMH Section C (Mental State Indicators) | Required for exploratory analysis about relationship between demonstrated symptoms/behaviours and sleep issues |

### Appendix C: Research Data and Record Destruction

## To be submitted once research has been approved and completed.

### Methods of Destruction:

|  |  |
| --- | --- |
| Check all that apply | Provide details on method |
| [ ]  Secure file deletions |       |
| [ ]  Other research data deletion |       |
| [ ]  Cross cut paper shredding |       |
| [ ]  Hard disk physical destruction |       |
| [ ]  Other physical media destruction |       |

### Approval

I hereby certify that all copies of the record(s) described above have been destroyed in the manner indicated.

|  |  |  |  |
| --- | --- | --- | --- |
| Signed: |       | Date: |       |
|  |  |  |  |
|  |       |  |       |
|  | Name |  | Title |

CPRI Research Agreement Approval Signature Page

Project Title:

Project Review Number:

|  |  |  |
| --- | --- | --- |
|       |  |       |
| Direct Manager (applicable only for internal applications) |  | Date |

Approval is needed by either the CPRI Director or the Research Review Committee members:

|  |  |  |
| --- | --- | --- |
|       |  |       |
| CPRI Director |  | Date |

Or

|  |  |  |
| --- | --- | --- |
|       |  |       |
| Applied Research & Education RepresentativeResearch Review Committee Member |  | Date |

|  |  |  |
| --- | --- | --- |
|       |  |       |
| Privacy RepresentativeResearch Review Committee Member |  | Date |

|  |  |  |
| --- | --- | --- |
|       |  |       |
| Psychology RepresentativeResearch Review Committee Member  |  | Date |