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RESEARCH BASED ON SECONDARY USE OF DATA OR BIOLOGICAL SAMPLES

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**This form is to be used for projects involving the proposed secondary use of data or samples where consent is sought to be waived.**

**Please note that if your research relies exclusively on secondary use of *anonymous* information or biological samples then REB review is not required unless the data or samples might reasonably be re- identified. Information or samples are “anonymous” if they never had identifiers associated with them (for example an anonymous survey) and the risk of identification of individuals is low or very low.**

**If identifiable data or samples are to be used, consent of the original donor is required unless ALL of the following conditions are met:**

* **It is essential to the research that data or samples be identifiable.**
* **You will comply with any known preferences previously expressed by individuals about the use of their information or samples.**
* **It is impossible or impractical to seek consent from individuals to whom the information relates.**

**Please direct all questions regarding the completion of this form to a Research Compliance Coordinator in the Carleton University Office of Research Ethics at:** [**ethics@carleton.ca**](mailto:ethics@carleton.ca)**.**

**Please submit the Secondary Use Form as a new application in CuResearch. If this form is to replace a Release of Funds, it should be submitted as an "Event" in CuResearch under the same study file. Please our** [**CuResearch User Manual**](https://carleton.ca/researchethics/submit-an-application/) **for directions on how to submit a new application or an event**.

Top of Form

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| 1. | | Title and Date | | |
| 1A | | **Project Title** | | |  | | --- | |  | |
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| 1B | | **Submission Date** | | Date of completion of this form. Update each time the form is revised. ([Detailed instructions](https://carleton.ca/researchethics/wp-content/uploads/Carleton-University-Research-Ethics-Form-Instructions-1B.htm), [Example](https://carleton.ca/researchethics/wp-content/uploads/Carleton-University-Research-Ethics-Form-Instructions-1B.htm))  Click or tap to enter a date. |
| 2. | | Project Team | | |
| 2A | | **Lead Researcher**   |  |  | | --- | --- | |  | Academic or Library Staff | |  | Post-doctoral Fellow | |  | Doctoral Student | |  | Masters Student | |  | Undergraduate Student | |  | Other | | | Last name/First name, Institutional Email, Department/Faculty and Institution (if not Carleton)   |  | | --- | |  |   If other, please describe   |  | | --- | |  | |
|  | | | | |
| 2B | | **Academic Supervisor**   |  |  | | --- | --- | |  | Not Applicable | | | Academic supervisor(s) Last name/First name, Institutional Email, Department/Faculty ([Detailed instructions](https://carleton.ca/researchethics/wp-content/uploads/Carleton-University-Research-Ethics-Form-Instructions-2B.htm), [Example](https://carleton.ca/researchethics/wp-content/uploads/Carleton-University-Research-Ethics-Form-Instructions-2B.htm)) (Note, the supervisor must be copied on all correspondence with CUREB.)   |  | | --- | |  | |
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| 2C | | **Project Team Members**   |  |  | | --- | --- | |  | No other team members | | | List the project team members: 1) Last name/First name 2) Email address 3) Role in project 4) Department and institution. (Please also indicate which members of the research team should be cc’ed on the ethics correspondence). ([Detailed instructions](https://carleton.ca/researchethics/wp-content/uploads/Carleton-University-Research-Ethics-Form-Instructions-2C.htm), [Example](https://carleton.ca/researchethics/wp-content/uploads/Carleton-University-Research-Ethics-Form-Instructions-2C.htm))   |  | | --- | |  | |
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| 3. | | Project Description | | |
| 3A | | **Is this Project Funded?**   |  |  | | --- | --- | |  | Yes | |  | No | | | If Yes, identify the source of the funding, the title of the award, the name of the award recipient and the CuResearch award number. (If this ethics protocol will replace a release of funds, please indicate the release of funds number).   |  | | --- | |  | |
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| 3B | | **Study Goal** | | Briefly explain the primary objective(s), rationale and potential benefits of the current study.   |  | | --- | |  | |
| 4. | | Summary of the Original Data or Sample Collection | | |
| **4A** | | **Source of Data** | | Who is providing the data or biological materials, or images? Provide the original protocol clearance letter, or the number and the date of clearance (approval), if available. Attach initial consent form if available. If this information is not available, please explain.   |  | | --- | |  | |
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| **4B** | | **Type of Data** | | What kinds of data or biological samples or images (e.g. medical files, blood samples, school records, etc.) will be used?   |  | | --- | |  | |
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| **4C** | | **Participants** | | Describe the characteristics of the participants from whom the information was originally collected (e.g. accountants working in government, people with asthma).   |  | | --- | |  | |
|  | | | | |
| **4D** | | **Other Permissions** | | Describe any permissions required for secondary use of this data or materials. If applicable, include copies of the relevant documents (e.g. contract/data sharing agreement, permission letter/email, other REBs or Institutional approvals). If not available, please explain   |  | | --- | |  | |
|  | | | | |
| **4E** | | **Donors’ Consent** | | What was the participants’ understanding of the use of the data or materials? Is this understanding consistent with the proposed use? If not, please explain.   |  | | --- | |  | |
| 5. | | Identifiability of Secondary Information | | |
| **5A** | **Privacy Protection** | | | Describe the physical (e.g. locked filing cabinet) and/or technical safeguards (e.g. encryption) that will be used to securely store the secondary information (e.g. written records, electronic data, recordings, etc.).   |  | | --- | | Click here to enter text. | |
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| **5B** | **Identifiability** | | | Characterize the type of secondary information or samples that will be obtained for research use.   |  |  |  | | --- | --- | --- | | **1** |  | Data or samples that can identify specific individuals either directly (eg. name, email address), or through a combination of indirect identifiers (e.g. DOB, IP address, postal code, rare diagnosis). | | **2** |  | Coded data, in which personal identifiers are removed and replaced with research identification numbers, but a separate code key is maintained linking personal identifiers to research identification numbers. | | **3** |  | Anonymized data in which no individual can reasonably be identified and the original identifiers have been permanently destroyed. |   **If you checked 1 above:** Answer questions in Section 6.  **If you checked 2 or 3 above:** Proceed to Section 7. |
| 6. | | Use of Identifiable Information (Complete only if you answered 1 to Question 5B) | | |
| **6A** | | **Risks to Donors** | | Could the secondary use of these data lead to any potential harm (e.g. physical, psychological, social, legal)? If yes, describe the nature of the potential harms and the measures you will take to minimize these harms.   |  | | --- | |  | |
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| **6B** | | **Data Security** | | Describe if and how the identity of the individuals will be safeguarded.   |  | | --- | |  | |
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| **6C** | | **Published Data** | | Will published data identify any study participants? (If yes, please explain)  Yes  No   |  | | --- | |  | |
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| **6D** | | **Retention of Data** | | How long will data be retained (or will it be retained indefinitely)?   |  | | --- | |  | |
| 7. | | Attachments | | |
| **7A** | | Documents to be submitted to the Research Ethics Board:   |  |  | | --- | --- | |  | The [TCPS CORE-2022](https://tcps2core.ca/welcome) tutorial certificate is required for each team member. If requesting an exemption, please justify below | |  | Sample of original consent document (if applicable) | |  | REB Clearance from the original study (if applicable) | |  | Permission letters, research contracts, data sharing agreements (if applicable) | |  | Supervisor approval form (if applicable) | |  | Other, please indicate in the field below |   Please explain:   |  | | --- | |  | | | |
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| **7B** | | | Provide a brief rationale if an attachment(s) is not available at time of submission.   |  | | --- | |  | | |
| 8. | | Declarations | | |
|  | | By submitting this form, the Lead Researcher and academic supervisor, if any, confirm that: | | |
|  | | * The information in this Form is correct and accurately describes the research project. * No analysis of the data or materials for this protocol will start before receiving ethics clearance. * I (we) willcarry out this project in accordance with the information in this Form and the other submitted documents. No changes will be made to the research project as described in this protocol without clearance from the Research Ethics Board. * I will promptly notifythe Research Ethics Board of any ethical or data breaches, adverse events, unanticipated problems, or protocol deviations that arise relating to this project. * This study meets all of the conditions for eligibility listed above. | | |
| 9. | | Comments | | |
|  | | | Do you have any comments or suggestions to improve this form?   |  | | --- | |  | | |

Bottom of Form