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**CHANGE TO A CLEARED RESEARCH PROTOCOL**

This form is to be used for amendments to a cleared protocol. Please direct all questions regarding the completion of this form to a Research Ethics Coordinator in the Carleton University Office of Research Ethics at: [ethics@carleton.ca](mailto:ethics@carleton.ca).

\* Please submit this form, an updated protocol form to reflect the changes and all accompanying documents as an "Event" in CuResearch under the same study file. Please see our [CuResearch User Manual](https://carleton.ca/researchethics/submit-an-application/) for directions on how to submit a new event.

\* Note that all of our forms are compatible with Microsoft Office. Students and staff members can download a free copy of MS Office at no charge: Students: <https://carleton.ca/its/ms-offer-students/> ; Staff/Faculty: <https://carleton.ca/its/all-services/computers/site-licensed-software/ms-offer-faculty/>

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|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 1. | | Project Information | | | | |
| 1A | | **Project Title** | | |  | | --- | |  | | | |
|  | | | | | | |
| 1B | | **Submission Date** | | Click or tap to enter a date. | | |
|  | | | | | | |
| 1C | | **Ethics Protocol #:** | | |  | | --- | |  | | | |
|  | | | | | | |
| 1D | | **Lead Researcher:** | | |  | | --- | |  | | | |
|  | | | | | | |
| 1E | | **Academic Supervisor (if applicable):** | | |  | | --- | |  | | | |
| 1F | | | **Is Carleton University the primary REB? If no, what institution cleared the study first:** | | |  | | --- | |  | | | |
| 2. | | Administrative Changes | | | | |
| 2A | | **Do you propose to change the title of the project? Yes  No**  **New title**   |  | | --- | |  | | | | | |
|  | | | | | | |
| 2B | | **Has your supervisor changed? Yes  No  N/A**  **If yes, new supervisor (include institutional email and Department/Faculty)**   |  | | --- | |  | | | | | |
|  | | | | | | |
| 2C | | **Have new team members been added? Yes  No**  If **Yes**: Please provide the name, department and contact information of the new researchers and ***submit copies of all documentation with the revised information.*** | | | | |
| |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Name** | **EMPLOYEE-STUDENT NUMBER** | **DEPARTMENT** | **CARLETON EMAIL** | **ROLE IN STUDY** | **TCPS2 TRAINING COMPLETE**  **(Y or N)** | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | | | | | | | |
| *To add a row, hover your mouse cursor to the bottom-left corner and click on the “+” button OR right click the cell and insert a row below.* | | | | | | |
| **2D** | |  |  | | --- | --- | | **Provide the name(s) of the team member(s) being removed.**   |  | | --- | |  | | | | | | |
| **2E** | |  |  | | --- | --- | | **Indicate the team members to be included in ethics correspondence on the file.**   |  | | --- | |  | | | | | | |
|  |  | | | | |
| 3. | | Other Changes | | | | |
| 3A | | **Instructions: Please answer Yes or No to the questions in Section 3. If you answer Yes to one or more questions, describe all these changes in Section 4A, and submit copies of all revised or new relevant documents.**  **Are you proposing to change the methodology or project design?**  **Yes  No** | | | | |
|  | | | | | | |
| 3B | | **Are you proposing to change the participant group for the project?**  **Yes  No** | | | | |
|  | | | | | | |
| 3C | | **Do you propose to change participant recruitment for the project or changes to any recruitment materials?**  **Yes  No** | | | | |
|  | | | | | | |
| 3D | | **Do you propose changes to questionnaire, survey, interview questions/themes or other data collection instruments?**  **Yes  No** | | | | |
|  | | | | | | |
| 3E | | **Do you propose to change the consent form(s) or materials (including addition or deletion of documents)?**  **Yes  No** | | | | |
|  | | | | | | |
| 3F | | **Are your proposed changes required by an external REB review? (e.g., changes to protocol, or adverse events, or protocol deviations mandated by an external REB.)**  **Yes  No**  If **Yes**: Please provide a copy of the correspondence from the external REB. | | | | |
|  | | | | | | |
| 3G | | **Are you proposing any other changes not mentioned above? Yes  No** | | | | |
| **4.** | | **Description of Changes** | | | | | |
| **4A** | | **Please describe all study changes here.**   |  | | --- | |  | | | | | | |
|  | | | | | | | |
| **4B** | | **Changes to the study may not be made prior to receiving ethics clearance unless required to advert serious harm to participants. If changes described here have been implemented, please justify.**   |  | | --- | |  | | | | | | |
|  | | | | | | | |
| **4C** | | **Does your research involve the use of *personal data* held by Carleton? If yes, you must complete a**[***security and confidentiality agreement***](https://carleton.ca/researchethics/wp-content/uploads/Security-and-Confidentiality-Agreement-of-PI-for-Research-CarletonU.pdf)**with the Carleton University Privacy Office prior to starting your research. The agreement is a contract between you and the university as to how you will manage the personal data throughout your research. If you have questions about the completion of this agreement, or best practices around privacy management for research, please contact the Carleton University Privacy Office by e-mail at**[***university\_privacy\_office@carleton.ca***](mailto:university_privacy_office@carleton.ca)**.**  **Yes  No**   |  | | --- | |  | | | | | | |
|  | | | | | | | |
| 5. | | 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 all changes to the research project. * No changes will be made before receiving ethics clearance, except to avert serious harm to any participant. * 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 Change without clearance from the Research Ethics Board. * I will promptly notifythe Research Ethics Board of any ethical or data breaches, adverse events, unanticipated problems, protocol deviations or complaints that arise relating to this project. | | | | |
| 6. | | **Attachments** | | | | |
| **6A** | | Documents submitted to the Research Ethics Board:   |  |  | | --- | --- | |  | The [TCPS CORE-2022](https://tcps2core.ca/welcome) tutorial certificate is required for each new team member. If requesting an exemption, please justify below | |  | Revised study materials with modifications highlighted (e.g. updated recruitment invitations, written consent forms or oral consent scripts, data collection instruments, and/or debriefing forms) | |  | Updated CUREB Protocol form with modifications to study procedures highlighted (e.g., CUREB Protocol form, Very Low Risk form, Secondary Use form) | |  | Supervisor approval form (if applicable) | |  | Other, please indicate in the field below |   Please explain:   |  | | --- | |  | | | | | |
| 7. | | Comments | | | | |
|  | | Do you have any comments or suggestions to improve this form?   |  | | --- | |  | | | | | | |

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