**AMENDMENT FORM for UNIVERSITY OF LETHBRIDGE**

Complete this form if you are proposing any changes from your approved ethics application.

**Instructions:**

1. Complete this Amendment form.
2. In the ARISE system, create a New Human Study.
3. In Section 1.1 (1.0) of the application form type **U of L AMENDMENT, Your U of L ethics ID, “Your study title”**.  This will clearly identify the application as an amendment application for an existing U of L HRPC approved application.
4. Using the U of L to U of A application mapping guidance, copy and paste the responses from your approved U of L application into the applicable sections of the ARISE application. As part of this ensure you clearly indicate what is changing.
5. Upload the following to the documentation section of the ARISE application:
   1. Approved ethics application including consent documentation/appendices
   2. Approval Certificate
   3. This completed Amendment form.

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| **UL Ethics ID:** | Click or tap here to enter text. |

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| **AMENDMENT DETAILS** |
| **1)** \* Outline the proposed changes to your approved research (a thorough description of the nature and details of the change(s) must be listed here, including, but not limited to, changes to the planned enrollment for the study, recruitment dates, number of participants, etc.) Please do not simply refer to any revised attached documentation. |
| Click or tap here to enter text. |
| **2)** \* Will your approved consent documents need to be revised as a result of this amendment? |
| Select a response. |
| **If YES**, provide a summary of changes here and attach the revised document to Section 7.1 of your application as well. You must attach BOTH a tracked change version of the revised document, as well as a clean copy for review/approval. |
| Click or tap here to enter text. |
| **3)** Do you currently have participants in the study who will need to be advised of these changes? |
| Select a response. |
| **If YES**, how will the participants be notified of the changes? |
| Click or tap here to enter text. |

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| **DOCUMENTATION REVISIONS** |
| **1)** \* Are you submitting any of the following revised or new documents? Select all that apply: |
| Not applicable  Consent or Assent Forms  Study Description/Protocol  Recruitment Materials  Letter of Initial Contact  Information Letter  Questionnaires, Surveys, Tests, Interview scripts  Other |
| **2)** Please provide a complete listing of all documents that you are submitting for review/approval with this amendment (including version dates if applicable): |
| Click or tap here to enter text. |