**Behavioural Amendment Coversheet**

Provide a summary of the changes to the Study (Application):

1) **Complete this coversheet.** In the sections below provide information about this amendment for which you are requesting approval. This coversheet (form) is to provide an overview of the amendment. The changes must be described in this coversheet and the **changes must then be entered into the appropriate sections of the application.**

2) **Edit the application.** If this is not done the amendment will be returned as incomplete. (e.g.: if submitting an amended research proposal, identify the document below and describe the changes, once you have completed the amendment coversheet then edit the applicable sections of the application form.) This is to ensure that, once approved, the application form will contain the current information for your study.

3) **Submit the Amendment.** When the above steps are completed the PI or one of the designated Co-investigators with Signing Authority must then submit the amendment. For instructions on how to designate a Co-Investigator with signing authority select [here](#).

<table>
<thead>
<tr>
<th>1.1 Proposed changes to study</th>
<th>Explain how the amendment relates to the original research question(s) and approved procedures.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.1.1 Briefly describe the nature of the proposed change(s).</strong> <em>(e.g. change in PI)</em></td>
<td>1.1.1. Explain what the change(s) are, using the following categories;</td>
</tr>
<tr>
<td>*</td>
<td>• <strong>Study design:</strong> changes to study objectives and procedures.</td>
</tr>
<tr>
<td>*</td>
<td>• <strong>Administrative changes:</strong> changes in study personnel, project title, sponsor, start or end dates, or any other similar changes. Please note that a change in the Primary Contact does not require the submission of an amendment.</td>
</tr>
<tr>
<td></td>
<td>1.1.2 Explain why each change was made (e.g. the previous PI has left the institution; interim results indicate a need to change the study objectives, etc.)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1.2 Risks to participants</th>
<th>1.2. Explain how the changes may or may affect participants or their potential willingness to continue in the study.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indicate whether or not the proposed changes will result in any increase in risk for the study participants beyond what was originally anticipated, and if so, please explain what the increased risks are and why they are necessary.</strong></td>
<td></td>
</tr>
</tbody>
</table>
1.3 Eligibility for delegated review

Does your amendment qualify for delegated review? (Please pick "Yes" or "No" after reviewing the guidance notes on the right).

- Yes
- No

Clear

Renewals and amendments to studies funded by the US funding agencies (e.g. DHHS, NCI) require full board review.

If your study is not funded by one of these agencies and the amendments do not involve any increase in risk to the participants beyond what was originally anticipated in the study, your amendment qualifies for delegated review, regardless of whether the study was originally submitted as a full board or minimal risk application.

If the amendment does involve a slight increase in risk beyond what was originally anticipated but the overall risks to participants fall within the minimal risk category, your amendment also qualifies for delegated review.

Click here for further information on the definition of minimal risk.

1.4 Progress of study

Describe briefly the status of the study and how far along you are in data collection and/or analysis.
**1.5 Principal Investigator**

Will the Principal Investigator (PI) be changed on the study?

- [ ] Yes
- [ ] No
- [ ] Clear

If "Yes", you must select here and complete the form with signatures then add the form below by clicking "Add".

Select "Add" to attach the signed letter for changing the Principal Investigator.

**1.6 Informed Consent**

Do the proposed changes to the study require any amendments to the consent process?

- [ ] Yes
- [ ] No
- [ ] N/A
- [ ] Clear

The N/A category would apply to studies involving no consent process (e.g. some types of secondary use of data or naturalistic observation).

To attach the updated consent documents go to section 9.2 of the application.

**1.7 Summary of Changes**

Complete each section below to provide an overview of the changes for which you are seeking approval. Upon completion of this form these changes must also be entered into the appropriate sections of the application

Revised or new documents:

List the revised or new documents being submitted and identify where the change(s) are in each document i.e., reference the section page.

Ensure that the changes in the documents are identifiable by
Are you submitting any of the following revised or new documents:

* Revised Proposal: ☐ Yes ☐ No Clear

* Revised consent and/or assent documents: ☐ Yes ☐ No Clear

* Other "revised" or "new" document(s): ☐ Yes ☐ No Clear

If "Yes", list each document(s) name and provide a brief summary describing the changes being made to that document. These changes must also be entered into the appropriate sections of the application form and clearly identified in the revised document after completing this coversheet. E.g. changes to the ICF to replace old PI's name with new PI's name.