

Annual Renewal Coversheet

*Important Note: this form is for renewing your study. If you would like to make changes to your study, you should submit a **Renewal with Amendment** form unless you are submitting your post-approval activity to the Providence Health Care Board, in which case you should fill out a study amendment form as well as the annual renewal form.

* 1.1. Eligibility for delegated review

Does this Annual Renewal qualify for delegated review? See guidance notes on the right for the criteria.

Yes No [Clear](#)

Studies funded by the US funding agencies (e.g. DHHS, NCI) require full board review. All other studies are eligible for expedited review.

1.2. Participant Recruitment

* 1.2.1.

Does this study involve the active recruitment of human participants?

Yes No [Clear](#)

(If "Yes", please answer the following questions in 1.2. If "No", please proceed to question 1.3.)

1.2.2.

Is recruitment ongoing?

Yes No [Clear](#)

Note: Please complete the following even if data collection is complete.

1.2.3.

Please enter the number of participants taking part in the study covered by this Research Ethics Approval.

Taken part to date:

Goal:

1.2.4.

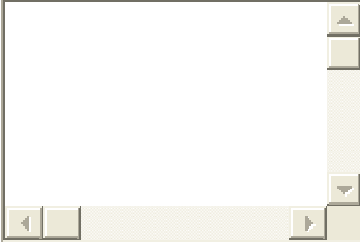
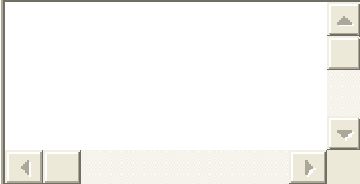
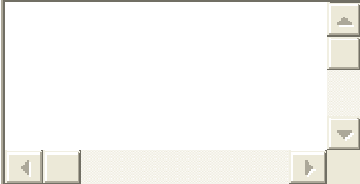
For multi-institution studies, please enter the number of participants taking part in the entire study (including centres outside of those applied for under this approval).

Taken part to date:

1.2.1. If your study is limited to an existing data set or naturalistic observation where no active recruitment is involved your response here would be "No" and you may proceed to question 1.3.

1.2.5. Participants are entitled to withdraw and are not required to give written notification, or to explain their reasons for such withdrawal. If, however, there have been any participant withdrawals and you are aware of the circumstances / the reasons, please indicate them.

<div style="border: 1px solid black; width: 50px; height: 20px; margin-bottom: 5px;"></div> <p>Goal:</p> <div style="border: 1px solid black; width: 50px; height: 20px; margin-bottom: 5px;"></div> <p>1.2.5. Have there been any participant withdrawals?</p> <p> <input type="radio"/> Yes <input type="radio"/> No Clear </p> <p><i>If so, please explain to the extent possible.</i></p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div>	
<p>1.3. Progress of Study</p> <p><i>Provide a brief summary of the progress of the study. This can include information on whether the recruitment of participants and/or fieldwork is going according to plan and any other details on whether the study implementation is meeting its timelines. If data collection is ongoing please provide details below.</i></p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div>	<p>The summary of progress to date should include information on whether participants are still being recruited in the research study or whether fieldwork is still being conducted (in the case of naturalistic observation and participant observation studies). For ongoing studies, remarks about the ability to recruit participants are also appropriate as is any information about the results from any interim analyses.</p>
<p>1.4. Unanticipated Problems</p> <p>* 1.4.1.</p> <p><i>After reading the definition of 'unanticipated problems' provided on the right, are there any unanticipated problems that you have experienced?</i></p> <p> <input type="radio"/> Yes <input type="radio"/> No Clear </p> <p>1.4.2.</p> <p><i>If "Yes", explain.</i></p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div>	<p>An unanticipated problem is any incident, experience, or outcome that meets all of the following criteria:</p> <ul style="list-style-type: none"> • Unexpected (in terms of nature, severity, or frequency); • Related or possibly related to participation in the research; • Suggests that the research places research participants or others at a greater risk of harm than was previously known or recognized. <p>For example, the theft of a laptop containing confidential information about participants would constitute an unanticipated problem; an</p>

	<p>outbreak war or insurrection in the area of the research might constitute an unanticipated problem.</p>
<p>1.5 Changes in Conflict of Interest</p> <p><i>Please provide details of any changes in relation to conflict of interest status of the Principal Investigator and/or other members of the study team.</i></p> 	
<p>1.6. Lapsed Studies</p> <p><i>If the study has expired and the renewal is being completed with the permission of the REB Chair or Manager, please provide a written explanation for the late renewal and confirmation that NO study related actions took place during the time over which there was no valid ethical approval, and explain what strategies have been put in place so that this will not happen in the future.</i></p> 	
<p>1.7. Additional Comments:</p> 