**HBCSE IRB EXTENSION FORM**

The IRB extension form needs to be submitted for continuing the existing research study beyond the initial IRB approval period i.e. the principal investigator/s wish to extend the same study (with NO NEW research subjects and continue to study the research data).

* If you plan to involve new research subjects (data collection) then you need to submit a fresh IRB application and NOT the extension form.
* The IRB extension period is of two years. Upon completion of the extension period, another extension of two years can be requested by completing the same form.

The IRB extension review will take about 1-1.5 weeks from the date of submission.

1) Provide the following information/details in order to review the extension application.

**Project title:**

**IRB approval number:**

**IRB approval start and end date:**

2) Write a summary of project for which IRB approval was received initially. (< 150 words)

Enter your text here

 3) Please indicate the number of participants currently approved. This number can be found in Section 2 (d) of your Initial IRB Application or Amendment if an increase in enrollment was requested.

Enter your text here

3a) Please indicate the number of participants enrolled in the study to date. You can choose to report the number using a table to indicate gender, age-group/class grade or any other distribution criteria used in your approved IRB application. (This data in collected only for IRB record keeping and reviewing section 5 entries if any)

Enter your text here

 4) Please describe whether the extension will impact the research subjects who have already participated in the study in any manner.

1. Will the extension necessitate requisition of re-consent from the research subjects? If Yes, please state why. If no, just say ‘no re-consent needed’
2. Will the proposed extension present any additional risks to research subjects? If yes, please provide details regarding the same.

Enter your text here

 5. Will the proposed change require that additional people will have to access to your research data. If yes, state their name and details.

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| --- | --- | --- | --- |
| **Name** | **Roll/duties in the project (e.g. data collection, transcript development etc.)** | **Current contact email** | **HBCSE or external member**  |
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5a. Please write details of how will you ensure the ethical norms (of data collection, data privacy etc.) that you have committed to (in the initial application form) will be communicated to and followed by the people included in Q5.

Enter your text here

6. Applicant’s name

7. Applicant’s signature

8. Name and signature of guide/PI (at HBCSE)

9. Date of IRB extension form submission (DD/MM/YYYY)