The continuing review serves as a time for quality improvement for the IRB, at which time they examine policies, procedures and performance to identify best practices and target areas in need of improvement; this includes implementation of corrective actions, changes to federal regulations or their interpretation, or policy changes where needed (Preserving Public Trust, 2001). As such, the continuing review is required to be as thorough as the initial review, and the IRB may require modifications prior to continued approval.

Continuing review applications should be submitted at least 30 days prior to the expiration date. If a completed form is not received by the expiration date, the HRPP office will close the file and all study related activities, including all data analysis, must stop.

Do not complete this application for studies determined to be **FLEX** or exempt, as continuing review of those studies is not required at OSU.

|  |
| --- |
| **SECTION 1 – Study Information** |
| 1 | Study Number |
|  | Insert response here |
| 2 | Study Title |
|  |  |
| 3 | Name of Principal Investigator  |
|  |  |
|  | Submissions will only be reviewed when received *directly* from the PI. |
| 4 | If the study was reviewed by the *full board* and included a plan to [certify](http://research.oregonstate.edu/irb/frequently-asked-questions/when-should-i-list-collaborators-study-team-members) study team members, list any individuals certified during the last approval period (N/A if study is expedited): | N/A |
|  |  | [ ]  |
| **SECTION 2 - Status**  | Check one |
| 1 | Recruitment has not begun | [ ]  |
| 2 | Actively recruiting participants and/or continuing to collect data or samples | [ ]  |
| 3 | Active participants but no new participants will be added (closed to enrollment) | [ ]  |
| 4 | Analysis of indirect and individually identifiable data or samples only (closed to enrollment or study did not involve enrolling participants). For more information on what constitutes identifiable data, see [HRPP’s Glossary of Research and IRB-Related Terms (Privacy, Confidentiality and Identifiers section](https://research.oregonstate.edu/irb/policies-and-guidance-investigators/guidance/glossary-research-related-terms)). | [ ]  |
| 5 | Analysis of data or samples AND you have destroyed or aggregated all indirect and individually identifiable information and/or any link between study data and subjects’ information. For more information on what constitutes identifiable data, see HRPP’s [Glossary of Research and IRB-Related Terms (Privacy, Confidentiality and Identifiers section](https://research.oregonstate.edu/irb/policies-and-guidance-investigators/guidance/glossary-research-related-terms)).\*  | [ ]  |
| \*If you checked box 5, your study is eligible to be closed, as the analysis of deidentified data does not constitute research with human subjects under the Common Rule (45 and 46.102) or OSU HRPP Policy and Procedures (9.2.1). Stop completing this form and complete the [Final Report](https://research.oregonstate.edu/sites/research.oregonstate.edu/files/irb/final_report_10102018.docx) form and submit it to irb@oregonstate.edu. Analysis of deidentified data or samples may continue indefinitely after the study is closed. If you are unsure if your study can be closed, contact the HRPP at irb@oregonstate.edu. |
| **SECTION 3 - Summary** |  |
| 1 | Provide a brief summary of the study progress to date. As applicable, include reasons for delay in study initiation, reasons for subjects withdrawing or being dropped prior to completing participation, progress at external institution(s) if OSU is not the only site.  |  |
|  |  |  |
| **SECTION 4 – Updates** | Yes | No | N/A |
| 1 | In the past year, have you identified any new risks or the potential for a decrease in benefits that may affect the willingness of current or future research subjects to participate in this project? If yes, describe the new information and how you will share it with current and future participants. | [ ]  | [ ]  | [ ]  |
|  |  |  |  |  |
| 2 | Do any members of the study team, or any of their family members, have a financial or other non-research interest in the source(s) of funding, materials, equipment, data, research subjects, or site of research related to this study that has not yet been disclosed to the IRB? If yes, please describe: | [ ]  | [ ]  |  |
|  |  |  |  |  |
| 3 | Have there been any participant complaints since the last approval? If yes, please explain: | [ ]  | [ ]  | [ ]  |
|  |  |  |  |  |
| 4 | Submit a Reportable Event form if there have there been any [deviations](http://research.oregonstate.edu/irb/post-approval) from the approved protocol during the last approval period that have not yet been reported to the IRB. |  |  | [ ]  |
| 5 | Submit a Reportable Event form if there have there been any [unanticipated problems or adverse events](http://research.oregonstate.edu/irb/post-approval) involving risks to subjects or others during the last approval period that have not yet been reported to the IRB. |  |  | [ ]  |
| **SECTION 5 – Documents and Reports** | Yes | No | N/A |
| 1 | Please indicate whether each item below applies to this study. If applicable, please include the document with your submission. |  |  |  |
| 1a | Copy of the most recently signed consent, assent and/or parental permission document.  |  |  | [ ]  |
|  | Ensure that the subject’s name is covered, but leave the date signed visible. |  |  |  |
| 1b | Copy of the informed consent document to be approved for the next approval period. |  |  | [ ]  |
|  | If changes are being made to the currently approved consent form, they must be made using track changes and a project revision form should be included. Do not submit a consent form if it is unchanged from the previous approval period or if the study is permanently closed to enrollment. |  |  |  |
| 1c | Copy of the external IRB approval and currently approved documents. |  |  | [ ]  |
| 1d | Current CLIA certification, if study involves returning clinical lab results to participants.  |  |  | [ ]  |
| 1e | Report from the Data and Safety Monitoring Board (DSMB) or similar, if one was planned or required. |  |  | [ ]  |
| **Complete the remainder of this form only if:*** **The study was reviewed by an expedited procedure AND has FDA-regulated components, or**
* **The study was reviewed by the full board**
 |
| **SECTION 6** **– Additional Updates**  |
| 1 | In the past year, has *anyone* other than the study team published new risks or the potential for a decrease in benefits related to the study activities or the study intervention? -If yes, provide a summary and citations for recent literature (published by this study team or others). Describe the new information and how it will be shared with current and future participants.-If no, describe how you made this determination. If you need assistance conducting a thorough literature search, please contact the [librarian](https://library.oregonstate.edu/staff/college-dept) for your college or school for assistance. | [ ]  | [ ]  |  |
|  |  |  |  |  |
| **SECTION 7 – Enrollment Numbers** |
| 1 | See the [FAQ](http://research.oregonstate.edu/irb/frequently-asked-questions/how-do-i-complete-enrollment-table-continuing-review-application-and) for detailed instructions and examples.  |
| 1a | Total number of participants approved for the study: |  |
|  |  | Total since LAST approval | Cumulative total since INITIAL approval |
| 1b | Number of subjects who consented to participation (total “enrolled”): |  |  |
| 1c | Number of subjects who screen failed or did no pass eligibility screening (“0” if no screening procedures): |  |  |
| 1d | Number of subjects who withdrew: |  |  |
| 1e | Number of subjects withdrawn by the PI: |  |  |
| 1f | Number of enrolled subjects who have not yet completed the study: |  |  |
| 1g | Number of enrolled subjects who have completed the study: |  |  |
| 1h | If OSU is not the only site, total number of subjects enrolled to-date across all sites, including OSU: |  |  |

**PI should email completed application and all relevant attachments to** **IRB@oregonstate.edu**