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 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 | Data or sample analysis only (closed to enrollment or study did not involve enrolling participants) | [ ]  |
| **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 | Have there been any participant complaints since the last approval? | [ ]  | [ ]  | [ ]  |
| 1a | If yes, please explain: |  |  | [ ]  |
|  |  |  |  |  |
| 2 | 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. |  |  | [ ]  |
| 3 | 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. |  |  | [ ]  |
| 4 | Has any new information been identified (e.g., risks or benefits) that may affect the willingness of current or future research subjects to participate in this project? | [ ]  | [ ]  |  |
| 4a | If yes, provide a summary and citations for recent literature (published by this study team or others), multi-center reports and/or Data Safety Monitoring Board reports. Describe the new information and how it will be shared with current and future participants. |  |  | [ ]  |
|  |  |  |  |  |
| 5 | Cite and summarize any relevant literature published during the past year, by the study team or others that may impact or change this study. If literature is cited, please explain how it impacts or changes the study. |  |  | [ ]  |
|  |  |  |  |  |
| 6 | 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? | [ ]  | [ ]  |  |
| 6a | If yes, please describe: |  |  | [ ]  |
|  |  |  |  |  |
| **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 – 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**