|  |
| --- |
| **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 approved protocol 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 (for studies requiring full board review) or since initial approval (for all other review levels): | N/A |
|  |  | [ ]  |
| **SECTION 2 – Study Outcome** | Yes | No | N/A |
| 1 | Briefly describe the outcome of the study: |  |  |  |
|  |  |  |  |  |
| 2 | Indicate the date project closed: |  |  |  |
|  |  |  |  |  |
| 3 | Reason for closing the project: |  |  |  |
|  | [ ]  Study Completed | [ ]  Funding ended | [ ]  Insufficient enrollment |  |  |  |
|  | [ ]  Other reason: |  |  |  |
|  |  |  |  |  |
| 4 | Have all research activities been concluded, including analysis of indirect and individually identifiable data? For more information on what constitutes identifiable data, see [HRPP’s Glossary of Research and IRB-Related Terns (Privacy, Confidentiality and Identifiers section](https://research.oregonstate.edu/irb/policies-and-guidance-investigators/guidance/glossary-research-related-terms)).  | [ ]  | [ ]  |  |
|  | If no, and the study remains **FLEX** or exempt, complete a **New Application and Protocol** form.If no, and the study is expedited or full board, complete a **Continuing Review Application**. |  |  |  |
| **Section 3 – Reportable Events** | Yes | No | N/A |
| 1 | Submit a Deviation form if there have there been any [deviations](http://research.oregonstate.edu/irb/post-approval) from the approved protocol that have not yet been reported to the IRB. |  |  | [ ]  |
| 2 | 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 that have not yet been reported to the IRB. |  |  | [ ]  |
| 3 | Have there been any participant complaints since the last review?  | [ ]  | [ ]  |  |
| 3a | If yes, describe complaint and resolution: |  |  | [ ]  |
|  |  |  |  |  |
| **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 4 – 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 form to** **IRB@oregonstate.edu**