|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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 data analysis? | | | | |  | |  |  |
|  | 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 | Have there been any participant complaints since the last review? | | | |  | | |  |  |
| 1a | If yes, describe complaint and resolution: | | | |  | | |  |  |
|  |  | | | |  | | |  |  |
| 2 | 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. | | | | |  | |  |  |
| 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 that have not yet been reported to the IRB. | | | | |  | |  |  |
| **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**](mailto:IRB@oregonstate.edu)