[Certain changes](http://research.oregonstate.edu/irb/post-approval) to **FLEX** and exempt studies can be made without IRB review.

**Use the track change feature of MS Word to incorporate proposed changes into all study documents impacted by the revisions. This includes listing any new study team members and their qualifications.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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. | | | | |
| **SECTION 2 – Nature of Proposed Change(s)** | | |  | | |
| 1 | *Check all that apply* | | | | |
|  | Change in Principal Investigator | Change in participant characteristics | | | |
|  | Adding study team members | Change in target enrollment number | | | |
|  | Removing study team members | Change in eligibility requirements | | | |
|  | Change in study design or objectives | Change to consent document or process | | | |
|  | Adding or removing study activities | Change to data collection or analysis | | | |
|  | Adding funding | Increase in risks or decrease in benefits | | | |
|  | Adding plans for future federal sponsorship | Adding a Certificate of Confidentiality | | | |
|  | Adding a FDA-regulated component | Adding a clinical intervention | | | |
|  | Other: | | | | |
|  |  | | | | |
| 2 | Details and justification for all proposed revision(s): | | | | |
|  |  | | | | |
| **SECTION 3 – Conflicts of Interest** | | | Yes | No | N/A |
| 1 | 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? | |  |  |  |
| 1a | If yes, describe: | |  |  |  |
|  |  | |  |  |  |
| **DO NOT INITIATE CHANGES TO THE STUDY OR PERSONNEL UNTIL YOU RECEIVE**  **A FORMAL APPROVAL NOTICE OR NOTIFICATION OF EXEMPTION RELATED TO THIS REVISION.** | | | | | |

**PI should email completed form and all relevant attachments to** [**IRB@oregonstate.edu**](mailto:IRB@oregonstate.edu)