**Please Note: All updated study documents must be included with the Change Review (modification) submission.**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Study type** | **PRMC Change Review Form** | **myIRB MOD Summary** | **Red-Lined Protocol**  **and Summary of Changes** | **Red-Lined Consent Form(s)** | **Updated (red-lined when available) Investigator’s Brochure and Summary of Changes** | **Updated Quality of Life/ Questionnaires** | **List of Updated Data Points**  **(Institutional WU and Non-WU trials only)** | **CIRB approval letter** |
| Interventional / Clinical Trial | √ | √ | \* | \* | \* | \* | \* | N/A |
| Retrospective Chart Review | √ | √ | N/A | N/A | N/A | N/A | N/A | N/A |
| Prospective Tissue/ Specimen Collection | √ | √ | \* | \* | N/A | \* | N/A | N/A |
| Survey / Questionnaire | √ | √ | \* | \* | N/A | \* | \* | N/A |
| Compassionate Use (only safety data collected) | √ | √ | \* | \* | \* | \* | \* | N/A |
| Cooperative Group Clinical Trial | √ | √ | \* | \* | \* | \* | N/A | \* |

\*= if applicable