**Modification Summary of Changes Template**

*The IRB encourages teams to use the following template to format summary of changes. Utilizing this format will ensure that all required information is provided to the IRB. Ensuring your summary includes this information facilitates the IRB review process in that it can: 1) decrease the amount of time it takes for IRB staff and members to review; and 2) decrease the likelihood of returns and questions. Please review the IRB’s Guidance:* [*How to Draft a Modification Summary of Changes*](https://irb.upenn.edu/how-submit-penn-irb/how-submit-modifications) *before utilizing this template.*

**Protocol Amendment Version #, Dated ##/##/####**

**Substantive (non-editorial) Protocol Changes**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Applicable Sections** | **Page No.** | **Summary of Changes** | **Rationale for Changes** | **Impact on ICF(s) (Y/N)** |
| Section 3 | 10 |  |  | Y |
| Section 4.1 | 20 |  |  | N |
| Section 5 | 25 |  |  | Y |
| Section 10 | 40 |  |  | N |

**[Product Name] Investigational Brochure Version #, Dated ##/##/####**

**Substantive (non-editorial) Investigator Brochure/ Package Insert Changes**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Applicable Sections** | **Page No.** | **Summary of Changes** | **Rationale for Changes** | **Impact on Protocol / Subject Safety (Y/N)** | **Impact on ICF(s) (Y/N)** |
| Section 3 | 10 |  |  |  | Y |
| Section 4.1 | 20 |  |  |  | N |
| Section 5 | 25 |  |  |  | Y |
| Section 10 | 40 |  |  |  | N |

**[Main/Screening/Part A] Consent Form Version #, Dated ##/##/####**

**Substantive (non-editorial) Consent Form Changes**

***Note: Please provide rationale for ICF changes when no protocol or IB amendment is accompanied by a revised ICF.***

|  |  |  |
| --- | --- | --- |
| **Applicable Sections** | **Page No.** | **Summary of Changes**  |
| 1. What is the purpose of this research study?
 | 2 |  |
| 1. What am I being asked to do?
 | 4 |  |
| 1. What are the possible risks or discomforts?
 | 10 |  |

*Remember to also identify any new documents and revisions to other materials, including any changes made in HSERA.*