Investigator’s Brochure/SmPC Review Template

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| **Study Title:** |  |
| **UoL Study Number:** |  |
| **IB/SmPC Version being reviewed:***(Specify IB or SmPC)* |  |
| *(Delete the appropriate row below and provide details of any changes if applicable)* **The above document has been reviewed and there are no changes required.** |
| **The above document has been reviewed and the following changes are required:** |
| **Does the Reference Safety Information require amending?**  | [ ] Yes[ ] No |

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| --- | --- |
| **Chief Investigator Name** |  |
| **Chief Investigator Signature** |  |
| **Date** |  |

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| --- | --- |
| **Clinical Trials Pharmacist Name** |  |
| **Clinical Trials Pharmacist Signature** |  |
| **Date** |  |

|  |  |
| --- | --- |
| **Sponsor Representative Name** |  |
| **Sponsor Representative Signature** |  |
| **Date** |  |