|  |  |  |
| --- | --- | --- |
| **Elements** | **Type of Study** | |
| **Retrospective Chart Review** | **Interventional Study** |
| **Introduction** | x | x |
| Background | x | x |
| Rationale/Significance | x | x |
| Problem Statement | x | x |
| Study Objectives | x | x |
|  |  |  |
| **Methods** | x | x |
| Hypothesis | x | x |
| Study Design | x | x |
| Outcome Variables | x | x |
| Study Population | x | x |
| Drug Information |  | x |
| Study Procedures | x | x |
| Study Schedule |  | x |
| Informed Consent |  | x |
| Screening |  | x |
| Recruitment, Enrollment and Retention |  | x |
| On Study Visits |  | x |
| End of Study and Follow-up |  | x |
| Statistical Method and Analysis | x | x |
| Sample Size Considerations | x | x |
| Institutional Review Board (IRB) Review | x | x |
| Data Safety Monitoring Plan |  | x |
| Funding Source |  | x |
|  |  |  |
| **References** | x | x |