**Proposal for content in protocol / synopsis**

Protocol Synopsis template:

Name of Sponsor

Address

Telephone number

E-mail address

Title and name of Principal Investigator

|  |  |
| --- | --- |
| Study Title |  |
| Study Rational and background |  |
| Study Objective |  |
| Study Design |  |
| In and Exclusion Criteria |  |
| Study Endpoints |  |
| Randomization & Stratification (if applicable) |  |
| Statistical Methods |  |
| Special Protocol Considerations (if applicable) |  |
| Sample Size |  |
| IMP, non-IMP, Comparators (if applicable) |  |
| Dose and route of administration(if applicable) |  |
| Description of Safety  |  |
| Timeline/milestone for study |  |
| Submission to Authorities |  |
| Plan for publication |  |