**1. Study title, Version & date**

Study title: ……….

Version: ……..

Date: ……..

**2. Principal and su**b- **investigators’ name**

 **Principal investigators’ name**

Full name: …………

Affiliation: ………

Tel: ………..

E mail: ………..

**Sub- investigators’ name**

1. Full name: …………

Affiliation: ………

1. Full name: …………

Affiliation: ………

1. Full name: …………

Affiliation: ………

**3. Sponsor and/or Source of funding**

…………..

**4. Protocol synopsis/protocol summary**

…………..

**5. Background and rationale**

…………..

**6. Study objective(s)**

…………..

**7. Study type/design**

…………..

**8. Study population**

**8.1  Eligibility criteria**

**8.1.1 Inclusion criteria**

1. ……
2. ……
3. ……

**8.1.2 Exclusion criteria**

1. ……
2. ……
3. ……

**8.1.3 Withdrawal criteria**

1. ……
2. ……
3. ……

**8.2  Number of participants and statistical determination**

……….

**9. Recruitment of participants**

……….

**10. Study setting**

……….

**11. Study method**

**11.1  Study intervention**

……….

**11.2  Study procedure, Variable and Study outcome/endpoint**

……….

**11.3  Safety monitoring plan and adverse event reporting**

……….

**12. Statistical analysis plan**

……….

**13. Research budget**

……….

**14. Ethical considerations**

**14.1 Regulatory and ethical compliance**

……..

**14.2   Informed consent process**

……..

**14.3   Risk/benefit assessment**

……..

**14.4   Vulnerability of participants and additional protection**

……..

**14.5  Payment/remuneration or incentive for study participation**

……..

**14.6  Medical care and compensation for study-related injury**

……..

**14.7  Privacy and confidentiality**

……..

**14.8  Community considerations**

……..

**14.9  Post-study care**

……..

**14.10 Collection of biospecimens and/or data for future studies**

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**14.11 Publication and data sharing policy**

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**14.12 Research registration (if applicable)**

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Sign..............................................Principal Investigator

Sign.............................................Co- Investigator

Sign..............................................Adviser (to be related)