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**Annexure 08/SOP-6/V3**

**Introduction:** (Need for the **Research protocol submission format to the SMVMCH-EC**

1. **Title of the Study** :
2. present study)
3. **Objectives:** (Primary and secondary)
4. **Review of literature:** (Study by study review from past to present)

Gaps in the literature, which the present study is going to address or specify the novelty, the present research

1. **Material and Methods:**

Setting:

Study design:

Study participants:

Study duration:

Sample size:

Sampling: (Sampling procedure, Inclusion\Exclusion Criteria, Blinding &

 Randomization)

Data collection procedure: (Questionnaire\Data collection proforma\ Details of

measurement\Biological sample collection)

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| --- | --- |
| **List of variables** | **Measurement plan** |
|  |  |

|  |  |
| --- | --- |
| **Anticipated Biases in the study** | **Plan to address the anticipated biases** |
|  |  |

Analysis plan**:** (Details on data entry and storage, Use of software - Name & Version)

|  |  |  |
| --- | --- | --- |
| **Variable** | **Name of variables** | **Analysis plan** |
|  |  |  |

1. **Implications of the study**
2. **Gantt chart:**
3. **Acknowledgements (if any):**

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technical support